THE INTERNATIONAL CENTRE FOR THE SETTLEMENT OF INVESTMENT DISPUTES

In the Matter of Arbitration Between: APOTEX HOLDINGS INC. and APOTEX INC., Claimants, and THE UNITED STATES OF AMERICA, Respondent.	Case No. ARB(AF)12/1 (Revised) Volume 6

HEARING ON JURISDICTION AND THE MERITS

Monday, November 25, 2013

The World Bank
1225 Connecticut Avenue, N.W.
C Building
Conference Room C8-150
Washington, D.C. 20433

The hearing in the above-entitled matter came on, pursuant to notice, at 9:00 a.m. before:

MR. V.V. VEEDER, QC, President

MR. J. WILLIAM ROWLEY, QC, Arbitrator

MR. JOHN R. CROOK, Arbitrator

Also Present:

MR. MONTY TAYLOR
Secretary to the Tribunal

MS. MARTINA POLASEK
Alternate Secretary of the Tribunal

Court Reporter:

MS. DAWN K. LARSON
Registered Diplomate Reporter
Realtime Reporter
B&B Reporters
529 14th Street, S.E.
Washington, D.C. 20003
(202) 544-1903

APPEARANCES:

Attending on behalf of the Claimants:

MR. BARTON LEGUM
MS. ANNE-SOPHIE DUFÊTRE
MS. BRITTANY GORDON
MS. LARA ELBORNO
Salans FMC SNR Denton Europe LLP
5 boulevard Malesherbes
75008 Paris
France

MR. JOHN J. HAY
MS. KRISTEN WEILMS
MS. ULYANA BARDYN
Dentons
1221 Avenue of the Americas
New York, NY 10020-1089
USA

Claimant's Representative:

MR. JEREMY DESAI
President and Chief Operating Officer
Apotex Inc.

MS. ROBERTA LOOMAR
General Counsel, U.S., Apotex Corp.

APPEARANCES: (Continued)

Attending on behalf of the Respondent:

MS. MARY McLEOD
Acting Legal Adviser
MS. LISA J. GROSH
Assistant Legal Adviser
MR. JOHN D. DALEY
Deputy Assistant Legal Adviser
MR. JEREMY K. SHARPE
Chief, Investment Arbitration,
Office of International Claims
and Investment Disputes
MR. NEALE H. BERGMAN
MR. DAVID M. BIGGE
MR. JOHN I. BLANCK
MS. ALICIA L. CATE
MS. NICOLE C. THORNTON
MS. ABBY L. LOUNSBERRY (Paralegal)
Attorney-Advisers,
Office of International Claims and
Investment Disputes
Office of the Legal Adviser
U.S. Department of State
Suite 203, South Building
2430 E Street, N.W.
Washington, D.C. 20037-2800
(202) 776-8443

C O N T E N T S

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P R O C E E D I N G S

PRESIDENT VEEDER: Good morning, ladies and gentlemen. We'll start Day 6 of this hearing, the 25th of November. There is a certain amount of housekeeping just to clear up over the weekend.

As intimated during the organizational meeting, the Tribunal sent a list of Topics to the Parties on Saturday, which appear to have been safely received. We also received some materials by e-mail from the Claimant. We understand there is no objection to those materials coming in to the extent that any new and particularly the single Authority referred to.

The arrangements for today are the Claimants will start their Closing Oral Submissions. And then we'll break, as agreed, and hear the Respondent's Closing Oral Submissions at 2:30.

Is there anything else from the Claimants' side that we need to address at the moment?

MR. LEGUM: A couple of small housekeeping matters.

The Tribunal Secretary asked the Parties to

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09:00:52 consult on the designations of confidential information in Day 5's rough transcript over the weekend. I'm afraid that the Parties were occupied by other matters, and so that homework assignment has not yet been completed. We will turn to it hopefully later today or at some point soon, but we haven't been able to get to that.

PRESIDENT VEEDER: I think we can say that that causes no difficulty to the Tribunal. It is just as, in fact, the Parties have raised, it may cause troubles for references to Day 5 of the transcript.

So it's been proposed, and we agree, that the pagination for today, Day 6, should start at 1600 and that will remain the standard reference for all future reference to today's transcript--I'm sorry, to today's transcript.

That would take care of it, wouldn't it?

MR. LEGUM: Actually, that was my suggestion.

PRESIDENT VEEDER: It was, indeed.

MR. LEGUM: And upon reflecting upon it further, I'm not sure that it works, actually. One would have to actually have the starting number for

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09:01:54 Day 5's transcript start with an even number for this to really work. I think.

PRESIDENT VEEDER: That we probably can't do, can we? Can we not live with Day 5 as it is?

MR. LEGUM: Well, in terms of--so two things. First, the Confidentiality Order agreed in this case allows for a certain period of time for the Parties to redact information before they are disclosed to the public. So, there, I think we're already covered.

In terms of the pagination references, that may be writing on the wall, I'm afraid.

PRESIDENT VEEDER: Okay. We've been defeated. We'll do what we can do.

We'll stop the transcript to talk to the shorthand writer.

(Conferring.)

PRESIDENT VEEDER: Anything else?

MR. LEGUM: I'm afraid there is. So two other things.

First, our slides today--we've been observing the way the Tribunal works with slides, and the Tribunal seems to be focused on the books. And I know

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09:04:35 that it's difficult to read small print. So what we've done is we've reproduced in their integrity certain documents so that they will be easier to read for the Tribunal. We'll flash on the screen so the people in the public room can see the documents, something, but there will be, in that sense, a slight discrepancy in that the format--the Tribunal's book and for opposing counsel's book, will be portrait. And it will be landscape--or maybe I've got that backwards in terms of the orientation of the pages. I just wanted to explain that so there is no confusion during the discussions.

PRESIDENT VEEDER: This looks fine to us. I know what you mean. There is more text.

MR. LEGUM: It's easier to read.

PRESIDENT VEEDER: It's easier to read. Thank you.

MR. LEGUM: Finally, on time--so the Parties have agreed on 90 minutes. With the Tribunal's questions, it may be a little bit tight. So the Parties have agreed that we'll have a little bit of latitude and, of course, any additional time that we

take, up to maybe ten minutes, the same courtesy should be extended to the United States.

PRESIDENT VEEDER: Does that cause any difficulty to the Respondent? It's agreed. On both sides we've added to burden of Closing Oral Submissions. We indicated on Friday that injury time would be extra to the 90 minutes. 10 minutes or so is no problem at all.

MR. LEGUM: Thank you.

PRESIDENT VEEDER: If you need longer, please say so.

MR. LEGUM: That's the end of my list.

PRESIDENT VEEDER: On the Respondent's side, is there any housekeeping we need to address at this stage?

MS. GROSH: No, we don't have anything further.

PRESIDENT VEEDER: Thank you very much.

Claimants have the floor for their Closing Oral Submissions. At some stage, you may want to take a break, but we'll let you decide when that should be.

MR. LEGUM: Thank you.

CLAIMANTS' CLOSING ORAL SUBMISSIONS

MR. LEGUM: Mr. President, Members of the Tribunal, a week ago today I opened the Claimants' Case-in-Chief by noting the exceptional nature of the U.S.'s treatment of Apotex and its investments. I did so not with Apotex's words, but with those of Edwin Rivera-Martinez.

Mr. Rivera, as the Tribunal will recall from the testimony of Lloyd Payne, was the FDA official who was on the phone once or twice a day with the inspectors during the Signet inspection in 2009. The Tribunal will recall what Mr. Rivera said about the Measure against Apotex. "That Import Alert was implemented 10 days after the completion of an inspection. We've never done that before. Generally, we place companies on an Import Alert after a Warning Letter. This inspection was completed on a Friday. On Monday, FDA Office of Compliance International Alert branch was on the phone with the executive officer and asked them what they intended to do."

Mr. President, Members of the Tribunal, a week ago I noted that FDA had never before and never

again rushed to take action against a major pharmaceutical company without any imminent health hazard and without providing any real opportunity for the company to address FDA's concerns. The evidence introduced and reviewed this past week, Apotex submits, has only confirmed that observation. None of the comparators identified by the U.S. presented either of these qualities. The Apotex case, as I noted last Monday, is, indeed, without equal.

The testimony and presentations this past week have underscored the insufficiency of the evidence offered by the U.S. in this case. We learned that Dr. Rosa, the only Witness supporting key portions of the U.S. position, had no personal knowledge of many of the matters addressed in his Witness Statement.

We heard a number of new factual arguments unsupported by any evidence, such as the newfound positions that cGMP violations for injectable drugs cannot be compared to solid dose, and cGMP violations by public companies are different from those that are not traded on stock exchanges.

Also notable is what we did not hear this week. Apotex showed in Mr. Hay's presentation on Monday that Janet Woodcock, the director of CDER, concluded in June of 2009 based on a hastily prepared Key Issues document, that Apotex should not be shipping drugs to the United States. Mr. Hay showed that Debra Autor, the Director of CDER's Office of Compliance, immediately asked Rick Friedman, the head of the Division of Manufacturing Products and Quality to attempt to put Apotex on Import Alert sooner rather than later.

We heard not one word from the U.S. last week about this critical exchange. Ms. Woodcock, Ms. Autor and Mr. Friedman are the FDA officials who made the decisions concerning Apotex at the relevant time, based on the input of Mr. Rivera. Given their personal knowledge of the decisions at issue, their absence as Witnesses in these proceedings is remarkable. This is particularly so given that Ms. Woodcock and Mr. Friedman are still active FDA officers.

We've also seen a series of contradictions

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develop between the U.S. case and the testimony given by its Witnesses. For example, the linchpin of the U.S. argument on National and MFN Treatment has, from the Counter-Memorial, been the supposed FDA risk-based approach described in Paragraph 20 of Dr. Rosa's First Witness Statement.

This referred, among other things, to the importance of "the firm's promised and ongoing Corrective Actions." In the Rejoinder and the Vodra Report, the main opportunity identified for Apotex to present a Corrective Action Plan was the August 17, 2009, teleconference, but Dr. Rosa made it clear last week that the August 17 call provided no such opportunity. That was not the purpose of the call. Instead, FDA's unstated agenda for the call was for Apotex to voluntarily agree to cut off all supplies to Apotex-U.S. from Etobicoke and Signet. The record shows that FDA provided Apotex no opportunity at all to propose a Corrective Plan before FDA decided on enforcement action.

Policy arguments are the last resort of an advocate struggling with the law or the facts. We

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heard many policy arguments this past week. We've heard a succession of parades of horribles. We've heard that FDA's discretion is subject to no review--we heard that from Mr. Vodra--and requiring it to respect the United States's international obligations under the NAFTA would endanger the public health. We heard that if FDA accorded treatment to covered investments in like circumstances as required by the NAFTA, FDA would no longer be able to take circumstances into account.

We heard that this Tribunal lacks the competence to carry out the mission clearly assigned to it under NAFTA Articles 1116 and 1117.

We heard that requiring States to provide the minimum procedural safeguards contemplated by international law would grind administrative decision making to a halt.

Mr. President, Members of the Tribunal, this is not a limit-testing case. Apotex's case under Articles 1102 and 1103 simply ask that the Tribunal apply the text of those provisions to the facts of this case. In our Presentation-in-Chief last week, we

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responded to the U.S.'s assertions that the sensitivity of FDA's mission was such that it should not be subject to National or MFN Treatment.

We showed that the NAFTA, in Article 1108, specifically allowed Parties to except Measures that were deemed too sensitive to be covered by National or MFN Treatment. We showed that Article 2101 provided a general exception from some NAFTA chapters for public health Measures. We showed that neither of these provisions provides an exception from Articles 1102 or 1103 for the FDA Measures hearing, confirming the NAFTA Parties' clear intent for those provisions to apply. The U.S. presentation, notably, did not address this showing.

In our presentation today, we will begin with Mr. Hay, who will address the facts. Ms. Dufêtre will then address jurisdiction. I will return to deal with National Treatment and Most-Favored-Nation Treatment, and then I will conclude with our observations on Article 1105.

I turn the floor, now, to Mr. Hay.

MR. HAY: Mr. President, Members of the

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Tribunal, good morning. My purpose today is not to rehash the facts that have been discussed at length during the previous five days of hearing. Rather, I will present some concluding remarks concerning the evidence adduced at the hearing and show that it demonstrates certain pertinent facts and also highlight the stark contrast between what the evidence shows and the allegations by the U.S. I have three points to discuss.

My first point is that the record clearly demonstrates that FDA did, indeed, rush to judgment. Apotex has shown that from as early as June 2009, even before the Etobicoke Warning Letter was issued, FDA was moving forward with the imposition of an Import Alert against Apotex. Consistent with the FDA's then new enforcement policy and based on a Key Issues Memo that was replete with uninvestigated suspicions and erroneous assumptions, CDER Director Janet Woodcock directed FDA to stop Apotex from shipping drugs to the U.S.

One alleged concern that the U.S. repeatedly returns to throughout these proceedings is the issue

of rejected batches. However, FDA never sought a clarification from Apotex concerning this issue until after the Etobicoke Warning Letter was issued. In addition, FDA's assertion that its real concern was the quality of Apotex's investigations of those rejections is disingenuous because FDA had not requested, much less reviewed, Apotex investigation files at the time. It is clear from the Etobicoke Warning Letter in which FDA requests copies of the investigation files.

It is hard to imagine a clearer case of a rush to judgment than FDA's condemnation of the quality of Apotex's investigations and based on the Etobicoke Warning Letter almost exclusively on the alleged deficiency of those investigations without having reviewed any documents relating to those very investigations.

Apotex also notes additional evidence in the record of FDA's rush to judgment, and that evidence relates to FDA's conduct with regard to the Signet inspection. The testimony of FDA's lead inspector, Mr. Payne, paints a very disturbing picture. A

pre-inspection conference with CDER with 30 people participating, discussing, in part, FDA's concern about cGMP violations at Signet even before the investigation began.

An FDA inspector, who frequently, if not daily, calls to the CDER office in many cases without other team members participating. That same inspector writing up observations even before she obtained the supporting documentation. That same inspector commenting to Mr. Payne before even commencing the inspection that they might "even have an observation before we get out there."

CDER discussing the Import Alert with inspectors during the inspection and Apotex being told at the closeout meeting to call CDER the next day to discuss how to address the deviations found, even though FDA began its work on the Import Alert before that call--in fact, even before the conclusion of the inspection.

As Mr. Payne commented later regarding the inspection, there is more to the story. It is apparent from this evidence that the Signet inspection

was not conducted for purposes of identifying deviations for corrections. Rather, its purpose was to identify cGMP deviations to support an Import Alert. FDA's judgment against Apotex had already been made.

My second observation concerns FDA's asserted reasons for the Import Alert. Apotex submits that the evidence shows that the reasons espoused by FDA for why it imposed Import Alert against Apotex are nothing more than post hoc rationalizations devoid of any evidentiary support. In its pleadings, Witness Statements, and presentations at the hearing, FDA asserted that the reason it put Apotex on Import Alert was because of Apotex's long history of repeated violations of cGMPs dating back to the 2006 Etobicoke inspection and its failure to keep its promises to institute corrective actions, which led FDA to believe it could not trust Apotex's commitments.

The contemporaneous documents, however, tell a different story. We respectfully refer the Tribunal to the Key Issues Memo--which is Exhibit C-358--which formed the basis for the Etobicoke Warning Letter and

Ms. Woodcock's view that Apotex should not be allowed to sell drugs in the U.S. We note that there is no mention in this document of the 2006 inspection, no mention of repeat violations, and no mention of Apotex's alleged failure to keep commitments.

We also point the Tribunal to the Etobicoke Warning Letter--which is Exhibit C-41--which similarly fails to mention any issue of repeat violations or failed commitments. This is in stark contrast to the Warning Letter of Apotex's comparators which specifically referenced the repeat violations of those companies and their failure to correct past violations despite their stated commitments to do so.

For this point, Apotex directs the Tribunal to the Sandoz Warning Letter in the record at Exhibit C-273 as an example of how FDA addresses repeat violations in Warning Letters.

And, finally, we direct the Tribunal to the August 20, 2009, memo from CDER to DIOP recommending the Import Alert--which is Exhibit C-64--and which, according to the U.S., formed the basis for DIOP's decision to implement the Import Alert. Again, the

reasons given by CDER for the Import Alert do not include any reference to past violations or failed--failure to meet commitments.

These documents make clear that FDA's basis for the Import Alert had nothing to do with past inspections or failed commitments. Rather, the Import Alert was based essentially on the Key Issues memo prepared by CDER.

FDA's newly created reasons are asserted in this proceeding evidently in the hope of deflecting the Tribunal's attention from the true reason behind the Import Alert, which was to demonstrate FDA's new tough enforcement policy and to provide an example which FDA could hold out for the world to see. In that regard, we remind the Tribunal that Apotex has provided evidence of the numerous occasions FDA pointed to the Apotex Import Alert as an unprecedented example of its new tough, swift, and visible enforcement policy. I respectfully refer the Tribunal to Exhibits C-51, C-65, C-527, C-529, C-531, and C-536.

The U.S., no doubt, also asserts that the

Import Alert was based on Apotex's history of repeat violations in order to support its decision to impose the Import Alert without first issuing a Warning Letter with respect to the Signet inspection. As the Tribunal may recall from my earlier presentation relating to FDA Regulatory Framework, the purpose of a Warning Letter is twofold; to give the firm notice that serious deviations from cGMPs were observed and must be corrected promptly, and to allow the firm an opportunity to explain itself and take voluntary corrective action.

However, the FDA can take more severe regulatory enforcement action before issuing a Warning Letter if it would be either unnecessary because the company's conduct is repeat, continuing, flagrant, intentional, or criminal, or if it would be inappropriate to issue a Warning Letter because of exigent circumstances.

In its presentation, the U.S. argues that because of Apotex's repeat violations, no Signet Warning Letter was necessary. And the reference there is--to the transcript is 659-660. However, as the

contemporaneous documents show, Apotex's prior history was not a consideration when FDA decided to impose the Import Alert.

My third point is that rather than validating FDA's actions, as the U.S. argues at Pages 608 and 609, the reaction of the world regulatory authorities to the Apotex Import Alert belies U.S. assertion concerning the health risks associated with Apotex's products and demonstrate the excess nature of FDA's conduct.

First, let's be clear as to what the record shows concerning how foreign authorities reacted to the Import Alert. As regards New Zealand and its regulatory authority, Medsafe, it negotiated with Apotex a voluntary temporary suspension of imports for what turned out to be one month for Signet and two months for Etobicoke. In announcing that agreement, Medsafe noted that these steps were precautionary. No recalls were required, and that Medsafe stated, "There is no reason for people to be concerned about taking any medicines manufactured by Apotex. There is no suggestion that people have been put at risk by taking

any medicines made at any Apotex plant."

Concerning the EU, the Netherlands Health Care Inspectorate similarly negotiated with Apotex a voluntary suspension of imports into Europe as a precaution. Like New Zealand, there was no recall of product, and with respect to Apotex's products, IGZ advised the public: "There are no reasons that would indicate any risk to the public for the products that have already been distributed in Europe."

Finally, TGA, the Australian regulator, also negotiated a voluntary suspension which lasted until Health Canada found the Apotex's facilities were cGMP compliant. When Health Canada did certify the facilities compliant, the voluntary suspensions, which lasted from two weeks in one case to two months in another, ended.

There were no Government-imposed import bans other than the FDA Import Alert. The U.S. assertion to the contrary is unsupported. Notably, the actions of these foreign authorities, as well as Health Canada, in continuing to allow customers to utilize Apotex's products and their public statements

attesting to the lack of health risk associated with Apotex's drugs contradicts the U.S. argument that the Import Alert was urgently needed because of health risks. Then again, FDA's own conduct also demonstrates that point, as noted by Mr. Bradshaw and Mr. Johnson in their Report. It is only the U.S. Legal argument in these proceedings that asserts otherwise.

In the same context, the U.S. asserts that Health Canada was considering revoking Apotex's license and imposing extraordinary terms and conditions, which the U.S. maintains proves Apotex's facilities were unsafe. There is no evidence in the record supporting either of these assertions or even describing the significance of the terms and conditions imposed. In any event, the record, in fact, shows the contrary. Health Canada allowed Apotex to continue to manufacture and sell product, further demonstrating that Apotex's products were safe. FDA was alone in taking such an aggressive stance against Apotex.

That concludes the fact portion of my

presentation. Unless the Tribunal has questions, I would ask that Ms. Dufêtre be called upon to discuss jurisdiction.

PRESIDENT VEEDER: Just one moment.

Not for the moment. Please continue.

MS. DUFÊTRE: Mr. President, Members of the Tribunal, I will now address jurisdiction.

All of the U.S. jurisdictional objections should be dismissed for the main reason that Apotex Holdings owns the enterprise Apotex-U.S., and Apotex's Marketing Authorizations qualify as investments.

I will start with Article 1101(1). There is no dispute that the Apotex Holdings is a Canadian investor with an investment in the United States, the enterprise Apotex-U.S. The U.S. jurisdictional objection on the basis of Article 1101 has no support on this record. What the record shows is that the Import Alert did, indeed, relate to Apotex-U.S. Apotex-U.S. was set up specifically as the marketing and distribution arm of Apotex in the U.S. Apotex-Canada sells its products exclusively through Apotex-U.S. in the United States.

FDA's Notices of Detention and Hearing were addressed to Apotex-U.S. directly, and this is in accordance with U.S. law and regulations as well as FDA's own guidance documents. All labels on Apotex's drugs sold on the U.S. market clearly identified Apotex-U.S. as the distributor of record. Apotex-U.S. depended on Etobicoke and Signet for 80 to 85 percent of its supply pre-Import Alert.

(Pause.)

MS. DUFÊTRE: So I was just saying that Apotex-U.S. depended on Etobicoke and Signet for 80 to 85 percent of its supply pre-Import Alert. Apotex-U.S. was the sole commercial importer of record of drugs from Etobicoke and Signet. The Import Alert prevented Apotex-U.S. from receiving any product made at Etobicoke and Signet, save for deferiprone.

The U.S. focuses on three drop shipments but ignores the clear evidence showing that these shipments were made by Apotex-Canada on behalf of Apotex-U.S.

Generally, the Import Alert decimated Apotex-U.S.'s sales. As a result, Apotex-U.S. dropped

out of the top 25 list of generic manufacturers in the United States, and Apotex-U.S. could not supply its customers; and, as a result, it had to pay very large penalties for failure to deliver.

So on this record, it is untenable to argue, as the U.S. does, that the Import Alert did not relate to Apotex-U.S. The Import Alert clearly did prevent Apotex from carrying on business for two years, which caused significant cash flow problems to the company.

The U.S. also fails to distinguish Cargill. Cargill had to comply with an import permit requirement in order to export high fructose corn syrup from its manufacturing facilities in the United States to its distribution subsidiary in Mexico. The Cargill Tribunal found that the dispute fell within the Scope and Coverage Clause of Chapter 11. The facts in Cargill closely resemble the facts of our case, as stated at Paragraph 136 of our Reply.

At the hearing last week, the U.S. advanced three new arguments in an attempt to distinguish Cargill. However, none of the U.S. arguments withstand scrutiny, and the argument can be found at

09:32:00 the transcript--rough transcript for Day 5 at Pages 95 and 96.

First, the U.S. argued that the U.S. investor, Cargill Inc., owned and controlled the local distribution company, which was the investment in Mexico. In contrast, the U.S. argues that Apotex-Canada does not own and control Apotex-U.S. However, the U.S.'s silence about Apotex Holdings--in our case, Apotex Holdings is the ultimate owner of Apotex-U.S., the local distribution company in the United States. Like Cargill Inc., Apotex Holdings owns and controls the local distribution company. Like Cargill de Mexico, Apotex-U.S. is an enterprise which is "primarily responsible for locating customers, negotiating Sales Contracts, delivering the products, and servicing customers." So the first argument raised by the U.S. fails to distinguish Cargill. To the contrary, Apotex is in a situation analogous to that of Cargill.

Second, the U.S. argued that the permit requirement was imposed in the host State on Cargill de Mexico--that is, the investment--as opposed

09:33:18 to the investor. Whether Cargill Inc. or Cargill de Mexico had to apply for the permit requirement, the Measure preventing Cargill products from crossing the border, does directly affect the business of the local distribution subsidiary.

The same is true for Apotex. Although the Import Alert is a Measure that prevented Apotex-Canada's products from crossing the border from Canada to the United States, it directly affected the business of Apotex-U.S. Apotex-U.S. resells Apotex products sourced from Canada. By preventing the importation of its sourced goods, the Measure affected Apotex Holdings's investment in the United States.

For this very same reason--that the Measure prevented the import of products in the host country--the U.S.'s third argument concerning Cargill must also fail. The U.S. argued that there was no legal impediment to Apotex-U.S. since the Import Alert allegedly did not interrupt Apotex-U.S.'s capacity to operate in the United States. But the U.S. ignores the fact that Apotex-U.S. depended on Apotex-Canada for 80 percent of its supply before the Import Alert.

09:34:42 Because of the Import Alert, Apotex-U.S.'s sales were decimated and Apotex-U.S. experienced financial difficulties. Like the import permit requirement in Cargill, the Import Alert constituted a legal impediment on Apotex-U.S.'s business in the United States.

In Cargill, when assessing the damages, the Tribunal also took a holistic view of the Cargill Group. The Apotex Group should also be viewed holistically, especially because it is a vertically integrated group of companies. Apotex-U.S. was set up specifically to distribute the Apotex products in the United States. Apotex Holdings, through intermediary companies, made significant investment into Apotex-U.S. to build it into a very successful business, ranking Number 6 on the U.S. generic drug market before being hit by the Import Alert.

To paraphrase the Cargill Tribunal, I would say, the inability of the operating company, Apotex-Canada, to export product to the distribution company, Apotex-U.S., is just the other side of the coin of the inability of Apotex-U.S. to operate as it

09:36:03 was intended to in the United States; that is, as a distribution company sourcing its products from Apotex-Canada.

On the whole, the U.S. fails to distinguish Cargill. On this record, the Import Alert did relate to Apotex-U.S. Apotex Holdings's claim passes the gateway of Article 1101(1) and can proceed to arbitration under Chapter 11.

Just a final remark on "relating to." The U.S. raised in its Rejoinder a new objection that there was not just one Measure, but, instead, three Measures. This objection was submitted after the Counter-Memorial and, for this reason, it is inadmissible under the Arbitration Rules governing this arbitration, and we made this point at Paragraph 31 of our Rejoinder on Jurisdiction.

During the hearing, U.S. counsel testified as to how this trinity of measures operates and how the Import Alert is supposed to fit in. And I refer to the rough transcript for Day 5 at Page 79. However, the U.S. has offered no support. As shown in Apotex's Rejoinder on Jurisdiction, Paragraph 32-41, the U.S.

point on the trinity of measures makes no sense.

Just to give you one example that arose from the U.S.'s presentation at the hearing last week, the U.S.'s new position is that Import Alerts are mere guidance documents and, as such, they cannot be the Measure preventing the import of goods across the U.S. border. And that is rough transcript for Day 5 at Page 102.

The U.S.'s position in this arbitration is contrary to U.S. case law that have held that Import Alerts are not mere guidance documents. In Bellarno versus FDA, FDA took the position that the Import Alert was just an interpretive rule or a general statement of policy. However, the Court did not agree with FDA, and the Court found that the Import Alert had a binding effect on both FDA and the importers. And this is at RLA-212 at Page 12.

In that case, FDA also pleaded that it was up to the border officers to decide whether or not to detain shipments and that not all shipments were automatically detained by virtue of the Import Alert. But, again, the U.S. Court rejected this argument,

finding that the Import Alert was a substantive rule of general applicability. Thus, in Bellarno, the U.S. Court rejected a very similar argument to the one the U.S. is trying to make in this arbitration. The record in no way supports the U.S. trinity of measures. All of the documents and exchange at the time referred to the Import Alert as the Measure preventing Apotex-U.S. from receiving any products from Etobicoke and Signet.

I now turn to Article 1139(g) and (h). Apotex demonstrated that its Marketing Authorizations are property under Article 1139(g), even if they can be revoked. The fact that Apotex Marketing Authorizations are revocable does not make them any less protected than any other property interest under Article 1139(g).

In fact, the Grand River Tribunal held that a U.S. trademark, which is a revocable property interest under U.S. law, constituted "investment" within the meaning of Article 1139(g). Like Arthur Montour in Grand River, Apotex owns a substantial business in the United States; that is, Apotex-U.S. Like in Grand

River, the distribution business in the U.S. sources its products from manufacturing facilities in Canada.

In our case, the Claimants do not own trademarks because generic drugs are not generally sold under a brand name or trademark. However, the Claimants own the Marketing Authorizations that enable them to distribute their drug products in the United States. Like trademarks, these Marketing Authorizations can be revoked, but they are nonetheless protected property under Article 1139(g) of the NAFTA.

With respect to Apotex's Marketing Authorizations as covered investment under Article 1139(h), I will make three brief observations. First, the U.S. conceded at the hearing that the term "interest" in that provision is not the same as property. That is rough transcript for Day 5 at Page 50. As demonstrated in our pleadings and in oral submissions, there is no doubt that Apotex's Marketing Authorizations constitute "interests."

Second, the U.S. also does not dispute that Apotex Holdings commits and contributes resources in

the United States to support its Marketing Authorizations, and these contributions are in the form of U.S. team employed in Weston, Florida.

Third, the Claimants emphasize that Apotex Holdings is the ultimate owner of Apotex's ANDAs. For instance, the point was made during Day 1--and this is transcript at Pages 72-73. Yet, in arbitration, when addressing Apotex's ANDAs, the U.S. did not say a Word on Apotex Holdings as the indirect owner. The U.S. observations were directed solely to Apotex-Canada, but ignored Apotex Holdings as an investor.

I now turn to the discussion of the Apotex I and II Award and the issue of res judicata.

I begin with Article 1136(1) of the NAFTA, which provides, "An Award made by a Tribunal shall have no binding force except between the disputing Parties and in respect of the particular case."

Under international law, res judicata will apply and provide a binding effect to a prior decision if three conditions are met: Identity of Parties, identity of cause, and identity of object or subject matter. In its Rejoinder, the U.S. argued that in

international law, res judicata includes the principle of issue estoppel. That's U.S. Rejoinder at Paragraph 99. During the hearing, the U.S. pleaded that issue estoppel is "acceptable on a worldwide basis, even though it is unknown in civil law jurisdiction." This is transcript Day 4 at Page 1181.

Contrary to the U.S. position, U.S.--issue estoppel does not form part of the doctrine of res judicata under international law for the mere reason that it is not custom or general principle, and scholarly writing seems split on this question.

As noted by Mr. Veeder, issue estoppel is not accepted everywhere in the world. The Authorities relied upon by the U.S. for the proposition that issue estoppel is part of the doctrine of res judicata in international law in fact undercut the U.S. position.

I will briefly address each of these Legal Authorities.

First, the U.S. relied on the ILA Recommendation, which is at RLA-282. However, as explained in Apotex's Rejoinder on Jurisdiction, the ILA Recommendations address the principle of

res judicata in International Commercial Arbitration, not in Investment Treaty Arbitration. And, moreover, these recommendations are de lege ferenda. They are not lex lata.

Second, the U.S. relies on the case of Haya de la Torre at RLA-271. The U.S. argued that the ICJ rejected Cuba's intervention to the extent that it dealt with questions that the Court had determined in the Asylum case and which were, thus, res judicata. However, in this case, the ICJ made it clear that the issues raised in the two cases were different.

In Haya de la Torre, the issue of surrender of Mr. de la Torre to Peru was a new issue which was not raised and not decided in the Asylum case. As such, the first judgment was not res judicata on this point. The two cases--the Asylum case and Haya de la Torre--were between the same Parties, Colombia and Peru. They arose out of the same set of facts, the asylum granted by Mr. De la Torre by the Colombian ambassador in Lima. And they were based on the same Treaty, the 1928 Havana Convention on asylum. However, these two cases did not address the same

issues, and the first judgment was not res judicata on the question of the surrender of Mr. de la Torre.

Third, the U.S. relied on the "Compagnie Général de L'Orinoque" (in French) at RLA-267. In this case, the umpire made a passing reference to a U.S. Supreme Court decision applying the common law concept of issue estoppel. However, the U.S. does not dispute that, in this case, the umpire was not asked to apply international law, but, rather, to decide all claims on the basis of absolute equity.

During the hearing, the U.S. did not dispute this fact. In fact, when asked about the Orinoco case, U.S. counsel instead pointed to Amco v. Indonesia, arguing that this latter case was decided both under both Indonesian law and international law. And this is the rough transcript for Day 5 at Page 17 and 18. Amco did not discuss--did, in fact, discuss the Orinoco case, but it found it not to be useful.

In sum, the Legal Authorities relied upon by the U.S. show that issue estoppel is not accepted as part of res judicata in every system of law. What is more, there is no clear international law practice

showing that res judicata extends beyond the dispositive of the reasons of a decision. And here I refer the Tribunal to the discussion in the Amco Decision on Jurisdiction in the resubmitted case, which is CLA-637 and the discussion is at Paragraphs 30-38. The reasons of a decision can help shed light on the dispositive part, but they do not themselves attract res judicata effect.

Even assuming that issue estoppel would be part of res judicata under international law, then what would be the exact contours of issue estoppel? The notion of issue estoppel does not have the same meaning, even among the common law countries. If we focus on the U.S. doctrine of Issue Estoppel, it will only apply if a right, question or fact was distinctly put in issue and directly determined by a court. And this was made clear in the Second Restatement on Judgments, which is at RLA-292.

The rights, questions or facts in the present arbitration were not put in issue and were not directly determined by the Apotex I and II Tribunal. The first arbitration was only concerned with two

pending applications for two specific drugs, sertraline and pravastatin, and their treatment by U.S. courts and FDA. In contrast, the present arbitration is concerned with the scores of finally approved Marketing Authorizations owned by Apotex-Canada and indirectly owned by Apotex Holdings. The issues in Apotex I and II and in the present arbitration are simply not the same.

During the hearing, the U.S. argued that Apotex could have raised the issue of its finally approved ANDAs in the Apotex I and II arbitration. This is transcript for Day 4 at Page 1198. There was no issue about Apotex's finally approved ANDAs in the first arbitration. The underlying dispute only implicated Apotex's sertraline and pravastatin pending ANDAs. It follows that the Claimants in this arbitration are not barred from raising the issue of the qualification of all of the Marketing Authorizations as investment for purposes of Chapter 11.

I will now turn to the specific Tribunal's question on this issue.

On Question A1, in Apotex's opinion, res judicata is not a jurisdictional objection. Apotex observes that the U.S. has not raised a jurisdictional objection on res judicata grounds. The issue in dispute here is the effect of the intervening Award in Apotex I and II on the present arbitration, and this issue should be resolved by Article 1136(1) of the NAFTA.

On Question A2, there is a distinction between derivative claims made on behalf of a company and claims made directly by a Shareholder on its own behalf. In this arbitration, Apotex Holdings brings a claim in its own right and in its own name. It is different from the claim made by Apotex-Canada. Apotex Holdings is bound by the Apotex I and II Award only to the extent that it addresses Apotex-Canada as the investor and holder of the two tentatively approved ANDAs at issue.

Apotex Holdings, through Apotex-U.S. and not Apotex-Canada, contributed to preparing, filing, and maintaining the Marketing Authorizations. Apotex Holdings invested in Apotex-Canada for that

purpose--sorry; invested in Apotex-U.S. for that purpose. Apotex Holdings's claim is, therefore, separate and distinct from that of Apotex-Canada.

And, finally, Apotex Holdings, as the indirect owner of the Marketing Authorization and as the indirect owner of Apotex-U.S., Apotex Holdings cannot be seen as a mere exporter of goods.

On Question A3 regarding the name of the Respondent in the two arbitrations, we respectfully submit that it does not make a difference.

On Question A4, as observed in Paragraph 38 of the Amco v. Indonesia Decision on Jurisdiction in the resubmitted case, "So far as international law practice is concerned, authors have not been able to show a clear trend towards the acceptance of reasons as res judicata." And, again, this is CLA-637.

Judge Anzilotti in the Chorzów Factory case made it clear that the--that only the operative part of a judgment is res judicata and binding. And that famous statement by Judge Anzilotti is now on the screen.

On that basis, Apotex respectfully submits

that, under international law, the second Tribunal may refer to the first Tribunal's Statement of Reasons to understand more clearly the operative part where those reasons are not expressly set out but implied in the operative part. However, only the operative part of the first decision is binding upon the Parties in that case.

Where the reasons are not expressly set out but implied in the operative part, the second Tribunal may consider the reasons of the first Tribunal's decision only to the extent that they constitute the necessary support for that decision or, to put it differently, insofar as they are necessary to determine the exact meaning of what is stated in the operative part. And here I refer to the Asteris v. Greece case that the Tribunal pointed to.

Moving on to Question A5, the UNCITRAL rules do not apply to the present arbitration, and NAFTA Article 1136(1) is the applicable provision on res judicata, and it requires a Triple Identity Test.

And, finally, on Question A6, the Parties, under Article 54 of the ICSID (Additional Facility)

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09:55:23 Arbitration Rules, the Parties have agreed that international law and not New York law shall apply to the specific legal issue. And, in addition, NAFTA Article 1131(1) provides that the Tribunal should apply international law.

This concludes my remarks, and unless the Tribunal has any further question, I will turn the floor back to Mr. Legum.

PRESIDENT VEEDER: Not at this stage. Thank you very much.

MR. LEGUM: It occurs to me that this may be a good time to take a short break.

PRESIDENT VEEDER: Let's take a 15-minute break. We'll come back at a quarter past 10:00.

MR. LEGUM: Very good.

(Brief recess.)

PRESIDENT VEEDER: Let's resume.

MR. LEGUM: Mr. President, Members of the Tribunal, I will now address Articles 1102 and 1103, the NAFTA's provisions on National and Most-Favored-Nation Treatment.

The record establishes that the U.S. violated

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10:11:46 these provisions by according Sandoz and Teva treatment more favorable than that accorded to Apotex and its investments. I will first address the U.S. arguments, then turn to Sandoz and Teva.

I begin with the element of "treatment" and the U.S. argument that Apotex's submissions are circular. I refer here to the rough transcript at 185 to 187. The U.S. distorts Apotex's submission here. Apotex's position is not that a legally significant connection between "measure" and "investment" establishes treatment. Our position is that the same factual record that we put in to show that the measure "relates to" Apotex-U.S. and the Marketing Authorizations establishes that those Measures were accorded treatment.

Ms. Dufêtre recalled that factual showing at the beginning of her presentation this morning. I need not repeat it here. The record clearly demonstrates that the Import Alert accorded treatment to Apotex and its investments.

The U.S. on Friday, for the first time in this arbitration, argued that Articles 1103 and 1102

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10:13:09 contained a previously unknown supplemental element; that in addition to meeting the express terms of these provisions, an investor must also demonstrate that "but for" its nationality of ownership, the investor would have received more favorable treatment from the State. It is telling that the U.S. felt a need to introduce such an element on Day 5 of a seven-day hearing. Its new element is without support.

Now, Apotex agrees that Articles 1102 and 1103 address nationality-based discrimination. These Articles do not address discrimination on the base of race, religion, gender, or other grounds sometimes regulated by international law. They are limited to nationality-based discrimination. The way in which they address this form of discrimination, however, is through the obligation set out in the text. Nothing in the text of these provisions supports the additional but-for element suggested by the U.S.

Now, the U.S. showed during its presentation a slide referring to the UPS case for this proposition of nationality-based discrimination. If you go back and look at that slide and look at the UPS Award,

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10:14:34 you'll see that those words don't actually appear in the UPS Award, so it appears to be a paraphrasing of that Award. So the UPS Award doesn't support it. And what is clear is that Articles 1102 and 1103 contain no element of intent to discriminate. It is hard to understand the U.S.'s new but-for test as anything other than an attempt to revisit this settled point.

This suggestion that Articles 1102 and 1103 should be amended to add a new but-for element is without support.

I come now to the U.S. argument that what Apotex advances here is a "one size fits all" approach that would require FDA to take enforcement action against all firms that receive a Warning Letter. And I refer here to the transcript of Page 618, and the rough transcript at Page 189. There are two points here: One of principle and one of evidence. On the point of principle, Apotex's position is clear: All circumstances are relevant, and there may be circumstances specific to a particular facility that FDA took into account that justify its treating otherwise comparable investors or investments

10:15:59 differently.

The role of this Tribunal is to weigh the circumstances shown through the evidence of record and decide this question. On the evidentiary point, this hearing has confirmed that a Warning Letter is a key evidentiary fact for purposes of like circumstances. Form 483 observations and those noted in an Establishment Inspection Report do not represent a determination by FDA that a facility violates cGMP. A Warning Letter by, by contrast, represents a finding by FDA of cGMP violations that make a firm eligible for an Import Alert.

This was a point that the U.S. emphasized in its presentations last week. Where was Apotex to find the essential reasoning why it was added to the Import Alert? The answer the U.S. repeatedly gave was this: In the unadorned statements in the Import Alert itself and in the Notices of Action that FDA had determined the facilities to violate cGMP. This was also the key fact that the U.S. pointed to its in trinity of measures objection. The finding of cGMP noncompliance in a Warning Letter establishes the eligibility of a

10:17:26 facility for an Import Alert.

All Parties, therefore, accept that a Warning Letter is important evidence for like circumstances. As I've noted, Apotex also accepts that other circumstances can be relevant; in particular, it accepts the relevance of circumstances FDA took into account for a given comparator. From the beginning of this arbitration, Apotex has been eager to debate whether the circumstances FDA took into account could justify the less favorable treatment accorded Apotex. This is what this Tribunal is here for. This is what this evidentiary hearing is about, reviewing the evidence, having a real debate about it. But that debate can occur only if the U.S. brings serious evidence concerning what specific circumstances FDA took into account and how it weighed the factors.

Apotex obviously does not know and cannot know what FDA was thinking. Only the U.S. knows that. Apotex cannot come forward with evidence as to what circumstances FDA took into account for Teva and Sandoz. Only the U.S. can do that. Apotex knows from the August 20, 2009, memorandum requesting the Import

10:18:50 Alert what circumstances FDA thought were relevant for Apotex and can compare those circumstances to the information that is available concerning FDA's treatment of Sandoz and Teva. But Apotex and this Tribunal can assess the specific circumstances FDA considered only if the U.S. brings evidence of those circumstances.

The U.S. has brought no serious evidence of those circumstances. I will review the record on Sandoz and Teva in a moment, but for now I recall that the record consists of newspaper articles, isolated e-mails, and testimony by a Witness who did not make the decisions and lacked personal knowledge on critical points. The Tribunal will need to review this evidence against the evidence that Apotex has adduced.

The Feldman versus Mexico Tribunal usefully addressed the weighing of evidence in the context of a claim that administrative enforcement action breached Article 1102. It observed that the Party who asserts a fact--whether the Claimant or Respondent--is responsible for providing proof thereof. The burden

10:20:11 of proof rests on the Party who asserts the affirmative of a claim or defense. And in the words of the Feldman Tribunal, "If that Party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other Party, who will fail unless it adduces sufficient evidence to rebut the presumption."

Now, the Rompetrol versus Romania Award is to similar effect, although it takes the view that the burden referred to by Feldman in the last sentence is one of persuasion rather than proof.

Mr. President, Members of the Tribunal, the record in this case more than establishes a presumption that Sandoz and Teva were in like circumstances with Apotex. Apotex accepts that it was open to the U.S. to counter that showing with evidence of the circumstances FDA took into account justifying different treatment. The evidence the U.S. has adduced is not sufficient to rebut Apotex's showing. I turn to that evidence now.

The U.S. does not dispute that Sandoz and Apotex are in like circumstances and that each had

U.S. investments that relied on foreign facilities for supply, and those facilities were found by FDA to be cGMP noncompliant and eligible for an Import Alert. Sandoz and Apotex are in like circumstances in significant other respects as well.

First, the Sandoz Warning Letter placed a heavy emphasis on Sandoz's failure to file Field Alert Reports, or FARs. Unlike Apotex, however, Sandoz did not just file FARs late, it failed to file them at all. I refer the Tribunal to Exhibit C-273, which is in your Hearing Books, and it's on the screen. The relevant passages for this point are highlighted in yellow.

Second, the Warning Letter cited Sandoz for failing adequately to investigate batch failures, a violation raised in the Etobicoke Warning Letter as well. This passage is highlighted in green. Unlike in the Etobicoke letter, the Sandoz letter explicitly noted that this was a repeat violation from two years before.

Third, the Warning Letter cited Sandoz for failure to establish appropriate procedures to prevent

microbiological contamination. This passage is highlighted in rose. This violation was not mentioned in the Etobicoke or Signet Warning Letters, but mentioned by Mr. Payne as one of his observations at Signet in his testimony on Wednesday. This was a repeat violation for Sandoz and noted as such in the Warning Letter.

Fourth, the Sandoz Warning Letter reflected a corporate approach by FDA. As the passage on Page 3 highlighted in blue shows, FDA emphasized that Sandoz's management had repeatedly failed to live up to promised Corrective Actions, noting multiple repeated violations from those cited in the August 2008 Warning Letter for Wilson and repeated observations from the previous inspection at Boucherville. It found that "neither upper management at Novartis nor at Sandoz-Canada ensured global, adequate, or timely resolution of the issues at these sites."

In addition, and unlike Apotex, Sandoz was offered multiple opportunities to respond to FDA's inspectional observations before the Warning Letter

was issued, as the text in orange on Page 1 of the Warning Letter shows. Perhaps most importantly, Sandoz Boucherville's products posed a health hazard. Crystallization in sterile injectable products, as noted in our Case-in-Chief and confirmed by Dr. Rosa, can result in severe patient injury.

The evidentiary record submitted by Apotex and confirmed in the Reports of Mr. Bradshaw and Mr. Johnson established that Sandoz was in like circumstances with Apotex and its investments. There is no dispute about the treatment Sandoz received: No enforcement action by FDA at all.

Now, I turn, now, to the U.S. Case-in-Response, which is summarized at Pages 235-238 of Day 5's rough transcript. The U.S. began with a new factual argument. The U.S. argued for the first time on Day 5 that, although Sandoz and Apotex are competitors and Sandoz Boucherville products--Sandoz Boucherville produces both injectable and solid dose drugs, Sandoz is not in like circumstances because the cGMP violations cited in the Warning Letter were only for injectable drugs.

Now, as is clear from the text highlighted in green on Page 3 of the Warning Letter, however, FDA stated unequivocally that the cGMP findings concerned all drugs manufactured at the facility, all of which were subject to refusal of admission, not just injectable products.

Moreover, there is no evidence to support this new assertion by the United States about injectables versus solid dose drugs. This is not covered in the Expert Reports. The U.S. at no point objected to Mr. Bradshaw and Mr. Johnson's reliance on comparators making injectables in its pleadings.

And on Wednesday, Mr. Goga made clear that, if anything, cGMP compliance was even more critical for sterile injectable than for solid-dose products because of the riskiness of those products. And I refer to the transcript at Pages 820-821.

The next argument made by the U.S. is that Sandoz Boucherville does not sell solid-dose products in the U.S. There is no records to--no evidence of record to support the U.S. proposition. Exhibit C-441 shows that Boucherville makes solid-dose products. In

the disclosure phase of this arbitration, Apotex asked the U.S. for documents showing what products Boucherville sold in the U.S., but the U.S. refused this request and produced nothing itself. The record does not support this late assertion by the U.S.

The U.S. then argues, presumably based on Dr. Rosa's Second Witness Statement, that Sandoz Canada offered to cease production and then ceased and slowed it. Well, first, as demonstrated in our Case-in-Chief, there was no shutdown at Sandoz Boucherville except for a short period following a fire.

Moreover, Dr. Rosa made it clear in cross-examination that he had no personal knowledge of Sandoz Boucherville and if specifics were needed, we would need to talk to someone else. This is the transcript at Pages 991-993.

There is no competent evidence establishing any offer on the part of Sandoz to FDA, much less the precise content and timing of the supposed offer. Nor is there competent evidence to support the U.S.'s assertion that medical necessity justified its more

favorable treatment of Sandoz. The record contains no drug shortage analysis, no e-mail, no competent testimony. There is no doubt that if either the offer to shut down or the drug shortage actually took place, the U.S. would have in its control authoritative documents and knowledgeable Witnesses to address them. The absence of either on this record is remarkable.

Finally, the U.S. points to a newspaper article saying that the Sandoz committed over $170 million U.S. to remediation efforts at this facility as well as the two in the U.S. Here, the double standard applied by the U.S. is evident. When Sandoz spends a substantial sum on remediation, it is a reason to grant it better treatment; when Apotex spends a huge amount on improving its systems, changes its quality leadership, hires a large new quality assurance staff, and invests time and care to restructure its quality systems, these are "admissions of systematic quality failures." And that reference is to the transcript at Page 678. The U.S. double standard aside, the record is clear: Apotex's remediation efforts were very substantial. It is in

like circumstances on this point.

In short, the U.S.'s evidence in no way rebuts the showing of like circumstance and less favorable treatment made by Apotex. Its claims under Articles 1102 and 1103 as concerns Sandoz are established on this record.

I turn, now, to Teva. Ms. Dufêtre addressed in detail why Teva is in like circumstances with Apotex on Day 2. I will not attempt to repeat that showing here. Instead, I will focus on the new evidence on Teva in the form of the PowerPoint presentation accompanying the October 28, 2010, meeting between Teva and FDA and the two specific arguments the U.S. advances to justify its different treatment of Teva.

I begin with the minutes of the October 2010 meeting which are in the record at C-424 and were reproduced integrally in the Hearing Books. The meeting was not limited to Irvine, but addressed global compliance, as you can see from the highlighted text on Pages 1, 3, and 4. Dr. Rosa, who at that time had responsibility only for international facilities,

was present and actively participated in this meeting, as the exchange on Page 4 shows. His focus was on what Teva was doing to fix global problems and concerns.

Turning to Page 5, FDA stated explicitly and directly what FDA expected--that what FDA expected was for Teva to offer to shut down any facility that was found to be noncompliant. The fact that this had to be stated implies that this expectation on FDA's part is not well-known, even to the largest generic pharmaceutical company in the world.

Turning now to the slide deck that is in the record at C-424(a), FDA reviewed Teva's compliance history at Slides 6 and 7, which are reproduced in the slide deck. The history included two Warning Letters, an injunction, and 15 inspections with Forms 483 issued beginning from 2005. The history included sites in the United States and sites outside the United States.

At Slide 44, the Teva recall trend is graphed, which shows an alarming increase in the number of recalls. Slides 45 and 46 concern tablets,

10:32:11 a form of product not produced at Teva Irvine but which was produced at Jerusalem. At Slide 48, the specific concerns FDA had are stated, including inadequate quality systems and inadequate failure investigations.

What this review shows is that FDA at the time was taking a global approach to Teva. Contrary to the U.S. argument, nothing in this record supports the distinction the U.S. attempts to draw between violations at Teva's U.S. facility in California and its facilities elsewhere. It also shows that Teva had repeatedly been given opportunities to correct its cGMP problems at multiple sites over multiple years and Teva still had grave issues despite this. What's more, Teva had substantial experience dealing with FDA enforcement, having received two Warning Letters and been the subject of an injunction in the past.

Most important, FDA told Teva point-blank that what it needed to say was--when future sites were found to be noncompliant was that it would suspend production that the site.

Now, Apotex by contrast, had never even

10:33:30 received a Warning Letter before 2009. It had no occasion to interact with CDER Compliance before the Etobicoke Warning Letter in June 2009. While Teva was given weeks to consider, consult with Experts, and prepare Corrective Action Plans, Apotex was given one business day to attempt to assess what CDER wanted and try to offer that. It had no opportunity to consult with Experts who could have advised it.

The U.S. makes two arguments why Teva's circumstances are not like those of Apotex. The first is on medical necessity and begins at Page 238 of Day 5's rough transcript. Now, the U.S. argues that Mr. Bradshaw and Mr. Johnson "do not take into account the following circumstances as set forth in a contemporaneous e-mail" referring there to R-131. I note that a related exchange is also in the record at Exhibit C-569.

The U.S. is correct about Mr. Bradshaw and Mr. Johnson not taking this e-mail into consideration. It would have been difficult for them to do so given that the e-mail in question was produced by the United States the week after they signed their Second Report

10:34:54 on May 24, 2013.

The U.S. relies exclusively on this one e-mail to demonstrate that Teva Jerusalem presented drug shortage issues. Dr. Rosa, in his Second Witness Statement, mentioned that drug shortages played a role in FDA's decision making on Teva, but his testimony on Wednesday made clear that he has no role in drug shortage analysis and he is not the person who makes the decisions on whether regulatory action should be deferred based on this ground. I refer to the transcript at Pages 832-833, 839, 844, and 1006.

Dr. Rosa testified that this e-mail did not reflect the kind of full drug shortage analysis on which a regulatory action decision could be based. I refer to the transcript at Page 1006-1008. Instead, it was just an offhand reaction of the drug shortage program to the announcement of a product recall by Teva. Dr. Rosa thought that a full drug shortage analysis was done for purposes of making a decision on whether to take regulatory action against Teva, but he had no more information about that. I refer to the transcript at Page 1008.

10:36:22 The record contains no competent evidence to support the U.S. assertion that a shortage of medically necessary drugs at Teva Jerusalem justified a difference in treatment as compared to Apotex. The record contains one e-mail that shows that the drug shortage program had concerns about the drugs involved in the recall of 30 batches produced by Teva Jerusalem. But no competent evidence shows that the decision on regulatory action for Teva was based on a shortage of medically necessary drugs.

It is also noteworthy that the U.S., in its presentation, did not dispute Apotex's showing that any shortage issues were a result of Teva's taking on market share of Apotex after FDA removed Apotex from the market. Nor has the U.S. in any way contested Apotex's showing that FDA could and often did except medically necessary drugs from an Import Alert.

Even if the record showed that drug shortage did play a role in FDA's regulatory action decision on Teva, nothing explains why every product Apotex made at Etobicoke and Signet had to be removed from the market save one, but every product at Teva Jerusalem

was sold without impediment.

The second argument advanced by the U.S. concerns Teva's response by FDA's concerns about Teva Jerusalem. Dr. Rosa received a call from Teva's head of quality. He was not clear about when the call took place other than that it was before the e-mail on the shortage implications of Teva's 30-batch recall in February of 2011. Dr. Rosa testified that Teva's head of quality offered to shut down production at the Jerusalem site. I refer to the transcript here at Pages 1032-1034.

Of course she did. That is exactly what FDA told her to do at the meeting on October 28, 2009. Teva's Executive Vice President for Corporate Quality was at that meeting, as both Slide 9 in Exhibit 424(a) and the minutes in Exhibit 424 demonstrate. FDA told Teva what to do. It did not tell Apotex. It did not give Apotex an opportunity to find out what FDA wanted. FDA demanded an answer from Apotex before it had a chance to reflect, consult Experts, or prepare a Corrective Plan.

Mr. President, Members of the Tribunal, what

this record shows is a difference in treatment, not a difference in circumstances.

Now, unless there are questions from the Tribunal, at this point I will turn to Article 1105.

PRESIDENT VEEDER: Forgive me. I didn't catch the name of the Teva executive vice President--

MR. LEGUM: Can we go back to the list?

PRESIDENT VEEDER: --who was present at the meeting in October.

MR. LEGUM: Frances Sakers, S-a-k-e-r-s.

And I believe in Dr. Rosa's testimony, he referred to Fran Zipp. I don't know whether that's the same person. I suspect it is, but there's no evidence in the record to clarify that point.

PRESIDENT VEEDER: Thank you.

ARBITRATOR ROWLEY: I've got one question.

Your last statement, you said "this shows a difference in treatment." And what I'm interested in is the word "treatment" used in 1102 and 1103, whether that, in your submissions, incorporates the way Apotex was dealt with in the inspection process or whether it's properly limited only to the Measure that is

adopted, if you see what I'm getting at.

MR. LEGUM: I guess my response would be that it is the Measure that was adopted as well as the Measures that were adopted with respect to the comparators and the manner in which those Measures were adopted.

PRESIDENT VEEDER: Thank you very much. It will come later.

MR. LEGUM: Mr. President, Members of the Tribunal, Apotex has fully presented its case under Article 1105 in its pleadings and in its oral submissions. The submissions from the U.S. that we heard on this topic on Friday did not respond to Apotex's case. Instead, it was an exercise in reimagining the case that Apotex has put. I will offer just a handful of observations before taking up the Tribunal's question under Article 1105.

So, first, contrary to the U.S.'s deliberate misreading, Apotex's pleadings are clear that the claims under Article 1105 are for treatment to Apotex's investments. I refer the Tribunal in particular to the Memorial, Paragraph 453 and 470, as

well as the Reply at Paragraphs 389 and 415. There is no merit to the United States's assertion at Page 249 of Day 5's rough transcript that "Apotex's allegations of failure of due process do not include either the ANDAs or Apotex Corp. within their scope."

Second, I'd like to address the United States's suggestion on Friday that it does not accept Article 1105(1)'s requirement of fair and equitable treatment to include an obligation to accord basic due process. And you have the text somewhere--yep. The text on the screen.

ARBITRATOR ROWLEY: This is a matter of interest. It says "Blanck" at the top, and mine is blank. Why are they blank?

MR. LEGUM: I believe that's a referral to the counsel on the United States team that delivered the argument.

MS. WEIL: We can reprint a slide for you with the image, and we apologize for that omission on that slide.

PRESIDENT VEEDER: I think you may need to explain that comment further. It is blank.

Come back to it later.

MR. LEGUM: Oh, I see. I apologize. I was looking at the screen--

PRESIDENT VEEDER: We thought it was a very subtle point.

(Laughter.)

MR. LEGUM: Okay. Thank you for clarifying that.

The U.S. suggestion that fair and equitable treatment does not include an obligation to accord basic due process is very difficult to understand. In every Free Trade Agreement or BIT signed by the U.S. since 2003, the Treaty has included a statement that "fair and equitable treatment includes the obligation not to deny justice in criminal, civil, or administrative adjudicatory proceedings in accordance with the principle of due process embodied in the principal legal systems of the world."

This provision, by its own terms, describes a part of the content of the customary international law Minimum Standard of Treatment of aliens. The denial by the United States before this Tribunal of any

obligation to provide basic due process cannot be reconciled with its Treaty practice with a score or more of countries around the world.

Third, Apotex's Memorial began its discussion of relevant international law with the Restatement Second of Foreign Relations Law. Its Reply began the same discussion with the Restatement. Apotex's oral submissions began with the Restatement. It is, therefore, difficult to understand how the United States in good faith could characterize Apotex's position as being based on one source that the Memorial addressed in a session collecting national administrative practice concordant with the rule of customary international law stated in the Restatement. This is not serious.

And, incidentally, the law school working paper that the U.S. referred to was, in fact, authored by a full professor of law and philosophy who holds the Albert Abel Chair at the University of Toronto. More importantly, the U.S. incorrectly described the substance of Apotex's argument as having evolved from its Memorial to its Reply and, once again, to this

hearing. This is incorrect. Apotex has consistently relied from the Memorial to the Reply to the hearing on the Restatement.

The U.S. also continues to ignore Apotex's position that the amount of due process required depends on context, a statement derived from the Restatement. The U.S. seemed to have understood this in its Counter-Memorial where, at Paragraph 370, it relied on the same Restatement comment as did Apotex. The U.S. appears to have forgotten what it once understood.

The U.S. also argued for the first time at this hearing that Apotex "has not provided any standards for the Tribunal, States, or Claimants to evaluate this would-be rule." I'm referring here to Page 290 of Day 5's rough transcript.

Apotex disagrees. The Restatement provides clear guidance on how much due process is due. Apotex would agree that the rule set out in the Restatement does not read like a national statutory enactment. In this, it is like other rules of customary international law. For example, it is accepted that

the obligation of full protection and security requires reasonable police protection under the circumstances. This obligation is not as specific as some national legislation, but its generality has caused no real difficulty.

The U.S.'s suggestion at Day 5 rough transcript Page 311 that "Government decision making would grind to a halt if the Restatement's rule were applied" is without support.

Fourth, the U.S. errs in suggesting that Apotex must demonstrate State practice and opinio juris in the specific context of the due process safeguards for drug importation Measures. This is not the way that customary international law works. No showing at such a level of granularity is required. The existence of the general rule recognized by the Restatement is sufficient. That rule is, as Apotex has already demonstrated, sufficiently flexible to apply to a wide variety of contexts, including this one.

Now, on Friday, the U.S. tried to point to other national regulators' reaction to FDA's placement

of Apotex on Import Alert as evidence of State practice. And I refer to the rough transcript at Pages 279-281. However, as demonstrated by Mr. Hay in his presentation this morning, these reactions do not demonstrate any State practice. Apotex voluntarily agreed to cease shipments to Australia, New Zealand, and the European economic area. A private Party's voluntary act cannot constitute State practice. Because Apotex acted voluntarily, there was no legal process and there is no evidence of the legal processes that these States provided to Apotex.

Fifth, the U.S. argued on Friday that Apotex erroneously omitted from consideration some of the Restatement factors. I refer to the rough transcript, Day 5, 288 to 289. In particular, the U.S. correctly noted that one of the factors is whether the Alien was allowed to consult with counsel. The U.S., in its oral submissions, further noted, correctly, that Apotex was represented by a skilled counsel from September 2009 and that Apotex did, in fact, consult with very experienced counsel. Apotex confirms that this is the case.

However, as we noted in response to a question from President Veeder on Wednesday, there is nothing in the record reflecting legal advice Apotex received about any of the four avenues the U.S. now suggests were available. This was, as we noted, because there was no such advice. It was not--simply not something that anyone at the time considered or considered to be available. The four avenues the U.S. proposes are so far from what any skilled counsel would consider that they were not even mentioned.

Mr. Bradshaw confirmed in his direct testimony that he was aware of no instance where an Import Alert imposed for drug cGMP violations based on an inspection had ever been successfully challenged through any of the four avenues.

Sixth--and I refer there to Day 5, rough transcript--that can't be right, so I won't refer to the transcript at this point.

Sixth, the testimony overwhelmingly confirmed that there was only one way of removing an Import Alert, through re-inspection. Mr. Bradshaw testified that "when a company is placed on Import Alert for

failures to comply with FDA's Good Manufacturing Practices, the only way to come off such an Import Alert is to remediate the manufacturing deficiencies and then to be re-inspected by FDA."

Dr. Rosa testified over and over that inspection was the only way to lift the Import Alert. When Dr. Rosa was asked about this, he answered that "that's the current policy we have in place"--at least since he has been at the center--"that, if an Import Alert is issued basis of the inspection, that would be the way to remove from the Import Alert."

Dr. Rosa went to say that "when you are dealing with a firm that has so many systemic cGMP problems, a re-inspection will be needed."

He further noted that the district officer would not be able to lift the Import Alert at a detention hearing because "nothing in the FDA happens by itself so a district office would not, on its own, take on that action."

In sum, no evidence suggests that anyone has ever successfully used any of the U.S. avenues. The only way FDA provides for an Import Alert to be

removed is through re-inspection. None of the four avenues were available to Apotex.

Finally, turning to the "effective means" provision of the U.S.-Jamaica BIT, the U.S. argument that Apotex had to exhaust means that were available to it misses the mark. None of those means were available to Apotex in this context. White Industries does not require Apotex to pursue avenues that end in a brick wall.

Now, I will conclude this portion of the discussion by addressing Tribunal Questions C1 and C2. The question is whether territoriality is a relevant legal factor for the rule of the customary international law invoked by the Claimants. And I should preface this remark by noting that the example given by the Tribunal suggests that the Tribunal may have a specific case in mind. We were not able to locate that case over the weekend, and so we may not fully understand it.

PRESIDENT VEEDER: You should have asked us. We did not have a specific case in mind. It was a specific example. That's all it is.

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10:54:33 MR. LEGUM: Okay. Good. All right.
So it is possible we don't fully understand the question, but the answer we would give is that the territory in which the treatment is accorded is relevant, but the territory where the alien is located is not. So if, as in this case, the relevant treatment where proceedings in the host State or the absence thereof, the treatment takes place in the host State, and a breach can occur whether the alien is personally in the host State at the time or not.
So if one thinks of the example of court proceedings, the mere fact that a Party in a court proceeding is not located physically in the country where the proceedings are taking place certainly does not mean that that country owes no obligations under international law to accord that alien of fair proceedings.
An example of this is the Rompetrol Group versus Romania case. There the Tribunal found a denial of fair and equitable treatment to a Dutch company based on abuse of actions by prosecutors in criminal proceedings in Romania against officers and

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10:55:52 directors of the Dutch company and of its local investments. The Dutch company at all times remained in the Netherlands. The Tribunal found that to the extent that the abuse of acts directly impacted the companies--the Dutch companies' interest as an investor, they breached the fair and equitable treatment obligation under the Treaty. So the reference is there with the paragraph references as well.
PRESIDENT VEEDER: I think the first paragraph refers to Rosinvest where'd you say the same thing happened. This was a treatment in the Russian Federation of the property interest, the investment of the Claimants, but none of the Claimants or their officers ever set foot in the Russian Federation.
MR. LEGUM: I imagine that is similar, although I have not looked at that case recently.
PRESIDENT VEEDER: Just take the visa case. If the treatment took place overseas, that would be the relevant geographical factor. If the treatment took place in the U.S.A., if it was a U.S. visa, then obviously you would say that crossed the line.

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10:56:54 MR. LEGUM: Or at least the territoriality requirement for this to be--to fall under the customary international law minimum standard of treatment of aliens would be implicated.
PRESIDENT VEEDER: Okay.
MR. LEGUM: All right. So turning to C2, which I think it should now be obvious, here the treatment was in U.S. territory. All the avenues identified by the U.S. involve either CDER in Maryland or the U.S. courts. It is in the host State that the proceedings took place, not elsewhere, and the fact that Apotex Holdings and Apotex-Canada were outside of the U.S. did not mean that they had no right to access to justice in the United States.
Well, this concludes our presentation on Article 1105 and our main presentation. I note that 90 minutes, of course, is not enough to address every issue in this case. So we have not covered everything that we've heard during the past week. I hope that the Tribunal will remember that we continue to rely on our other submissions.
Speaking of submissions, there was a question

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10:58:00 about submissions, so I think we have slides here that should be in your Hearing Books that set out the detailed submissions that we would offer, both as concerns this phase of the proceedings and the next phase of the proceedings, which we hope will take place.
I'm happy to review those with the Tribunal or to answer any questions about them.
PRESIDENT VEEDER: One question on 1105, that is your submissions for the final award under Paragraph 1B, your original damages claim has been slightly modified by later events, but is there a figure, even a ballpark figure, for that damages figure? Come back to it later if it's a question that has caught you and you need consider. But what is roughly the figure or figures?
MR. LEGUM: I would say that it's between 1 billion and 1.5 billion based on information that was available as of early 2013. Obviously that information would need to be updated to reflect additional information.
PRESIDENT VEEDER: In the language of

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10:59:20 Paragraph 1B, that includes pre-award interest, or does it exclude it?

MR. LEGUM: I don't remember at this point.

PRESIDENT VEEDER: Okay. Thank you.

QUESTIONS FROM THE TRIBUNAL

ARBITRATOR CROOK: I'd like to revert to 1101 very quickly. I haven't looked at the Friday transcript, so my memory here may be defective. If so, so be it. I recall in there discussion of legally significant connection what was at least an implicit suggestion, if not explicit, that the legally significant connection was to be found in the direct application of the contested measure to a particular investor/investment. And, perhaps, that's not the argument they're making. They'll tell us, but I saw some element of that. So they were looking for direct legal operation rather than the more general sorts of arguments that you have been making as the consequence but, perhaps, not as the direct legal effect, bad things happen. As I say, perhaps I have misunderstood their argument, but should that be their argument, what would be your views on that?

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11:00:47 MR. LEGUM: I guess our response is we initially thought that that was their argument, and we responded to that argument, in other words, in our Reply.

ARBITRATOR CROOK: In due course, if you can point us to where we find that, that would be helpful. Thank you.

MR. LEGUM: Certainly. But, yes, we initially thought that the U.S. was arguing that what was required by the provision was that it directly applied to the Measure, and we responded to that by pointing to the fact that, in fact, the Measures implicating the Acts implementing the Import Alert, such as the notice of action of detained products were addressed directly to Apotex-U.S. as well as to Apotex-Canada. And under U.S. law, for Import Measures such as this, U.S. law requires notice to be provided both to a consignee, such as Apotex-U.S., as well as to Apotex-Canada. And so the evidence of record in this case shows that the Measure was directly applied to Apotex-Canada. In fact, under U.S. law it recognized that it had noticed--it should

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11:01:59 be given notice of the Measure. But we'll be happy to get back to you with specific references to our pleadings on that.

PRESIDENT VEEDER: One further question for Ms. Dufêtre. It really relates to the answer you gave this morning to the Tribunal's question A5. It's at Slide 63 of your PowerPoints. You'll also need a copy of the Award in Apotex I and II if you have that at hand.

Now, let's take this slowly because I'm concerned that maybe we didn't get our message across because we understand this to be the argument of the Respondent. If you look at Apotex I and II Award, it's based upon an Arbitration Agreement between the named Parties to that arbitration, Apotex Inc., and as simplified, United States of America. That Arbitration Agreement included the 1976 UNCITRAL Arbitration Rules. If you look at those Rules, what we see in Article 32(2) is that the Award is to be final and binding; that is, on the named Parties to the arbitration, here Apotex Inc. and the United States of America.

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11:03:41 If you look at Article 32(3), we see that the Award includes reasons upon which the Award is based. Now, if you were to ask a layman, "Does the Award include reasons?" He would say--or she--"Yes, it does. That's what the Rules provide." "Is the Award including the reasons final and binding upon the named Parties?" And he or she would say, "Yes, that's what the Rules provide."

So before you come anywhere near our case, is it possible that out of the Apotex I and II Award you have an agreement between the named Parties to that arbitration to treat the operative part and the reasons both forming part of the Award as final and binding upon them as a form of lex specialis independent of any lex arbitri or, indeed, international law? I'm not saying that's right or wrong, but if that were so, then Apotex in coming to these proceedings with the United States, would it be, in effect, contractually bound to respect the reasons and the operative part in the Apotex I and II Award? Again, independent of any lex arbitri or, indeed, any national or international principles or rules of law.

That was the question. It's not really res judicata, although it comes under that umbrella, but obviously it has a similar effect.

MS. DUFÊTRE: Yes, I apologize. This is not how we understood and interpreted that question. So with your permission, if I could have a few moments.

MR. LEGUM: I think I can answer your question.

PRESIDENT VEEDER: It might not be helpful as Ms. Dufêtre, but please go ahead.

(Laughter.)

MR. LEGUM: My answers aren't usually as helpful as those of Ms. Dufêtre. I confess that.

Article 1120 of the NAFTA provides for the possibility of submitting a claim under the UNCITRAL Arbitration Rules in Paragraph 1. Paragraph 2 of Article 1120 reads, "The applicable Arbitration Rules shall govern the arbitration except to the extent modified by this section."

So it wasn't the unabridged 1976 UNCITRAL Rules that governed the first proceeding. It was the 1976 UNCITRAL Rules to the extent modified by this

section. This section, of course, is Section B on "Settlement of Disputes Between a Party and Investor of Another Party," and Section B includes, among its numerous articles, Article 1136(1). So our submission would be the Arbitration Agreement and the Arbitration Rules applicable to that first arbitration was not just the 1976 UNCITRAL Rules but, as a contractual matter, it also included the terms of Section B of Chapter 11 and the Rules stated in Article 1136(1).

Does that help? It wasn't as helpful as Ms. Dufêtre.

PRESIDENT VEEDER: You have to go on. So what is the effect of that? You aren't saying that the Apotex I and II Award does not include reasons and that it's not final and binding upon Apotex Inc. and the United States?

MR. LEGUM: No.

PRESIDENT VEEDER: So to what extent does the legal status of that agreement by those Parties affect the position of these two Parties in this arbitration?

MR. LEGUM: In terms of the binding effect of the Award, I think neither one of those two provisions

directly addresses the binding effect of an Arbitration Award as between the Parties. Article 1136(1) directly addresses the binding effect of an Arbitral Award, and we would submit that Article 1136(1) refers to the Triple Identity Test and public international law, and that's how that question should be decided.

PRESIDENT VEEDER: Okay. Thank you very much.

Well, thank you all very much. We've come to the end of the Claimants' Closing Oral Submissions. Unless there is something else we need to address now, we'll break until 2:30 and hear the Respondent's Closing Oral Submissions.

MS. GROSH: Mr. President, thank you. Would it be possible to have an additional 15 minutes in light of the fact we went over a bit?

PRESIDENT VEEDER: You mean we start at 2:45 p.m.?

MS. GROSH: At 2:45.

PRESIDENT VEEDER: Yes, of course.

MS. GROSH: Okay. Thank you very much.

(Whereupon, at 11:08 a.m., the hearing was adjourned until 2:45 p.m., the same day.)

AFTERNOON SESSION

PRESIDENT VEEDER: Let's resume. Respondents have the floor for their Closing Oral Submissions.

MR. DALEY: Thank you Mr. President.

Mr. President, Members of the Tribunal, I will begin our Closing Arguments this afternoon. I will be followed by Ms. Grosh, who will address the questions posed by the Tribunal on Saturday. Following that, Mr. Sharpe will address the implications for Apotex's arguments--implications of Apotex's arguments for the three NAFTA Parties. And, finally, Ms. McLeod will address--make some concluding observations.

I would like to begin our remarks this afternoon by placing this case in the broader, legal, and institutional context. I will then briefly touch upon the facts. You heard a lot of testimony and argument last week, and we are mindful not to be redundant, but Mr. Hay's summary this morning raised a few points that must be corrected.

Now, as for the first point, the regulatory context of this case is clear and undisputed, as we

14:57:13 discussed in Pages 10-29 of our Counter-Memorial.

Over 150 years ago, Congress enacted legislation authorizing the U.S. Government to refuse to admit adulterated drugs offered for import. In 1938, that Rule became part of the Federal Food, Drug, and Cosmetic Act, the law that created the "appearance of adulteration" standard. Under the 1962 Amendments to that law, any drug manufactured at a non-cGMP-compliant facility is a legally deemed to be adulterated.

Apotex itself has acknowledged that under U.S. law, a drug is considered adulterated if the methods or facilities used to produce it do not conform to cGMP so as to ensure the safety, identity, strength, quality, and purity of the drug.

A drug deemed to be adulterated may be detained without physical examination and refused admission into the United States. Or, as Apotex has put it, U.S. law grants FDA the authority to refuse admission of goods offered for import if they appear adulterated.

FDA's Import Alert policy has been in effect

14:58:22 since at least the 1970s. Apotex does not and cannot dispute this any less than it can dispute that its own drugs were subject to an Import Alert over 20 years ago in 1992. That is discussed in Paragraph 58 of our Counter-Memorial.

The FDA's standards for cGMP are widely emulated around the world, including by the World Health Organization. FDA coordinates closely with agencies in other countries, most of whom have cGMP standards similar to the United States. In 2012, the Generic Pharmaceutical Association described FDA's work in the area of generic pharmaceutical inspections as "extraordinary."

Now, that association is the trade association of which Apotex itself is a member. One of Apotex's own Witnesses in this case, Mr. Watson, sits on its board. In testimony before the U.S. Congress--which is at Exhibit R-94--a representative from the Generic Pharmaceuticals Association explained, "The U.S. drug supply remains the safest anywhere in the world, and the FDA's drug approval and inspection process represent the gold standard for

14:59:29 regulatory agencies worldwide."

FDA's activities have taken on a whole new dimension due to globalization. A few decades ago, the United States imported relatively few drug products. Today, approximately 40 percent of finished drug products and 80 percent of Active Pharmaceutical Ingredients, or API, come from more than 100 countries around the world. And this has required FDA to engage in a difficult and complicated balancing of risk.

On the one hand, there is a heightened risk of adulterated product entering the United States. The challenges of the globalized drug industry were highlighted by the heparin scandal in 2007, which Dr. Rosa touched upon in his testimony at Pages 1024, 1076, and 1077. Starting in 2007, scores of people died and hundreds developed severe allergic reactions in 11 countries due to the use of adulterated heparin, which is an anticlotting drug widely used for surgery and dialysis.

FDA identified a contaminant in the drug's API, which was made at a facility in China. Although the Chinese facility had manufactured API for the

15:00:47 United States market since 2004, FDA had never inspected this facility. When FDA did so in February 2008, it discovered significant deviations from cGMP. Indeed, FDA had to create a new Import Alert just for heparin-related products, and the Agency put 34 Chinese facilities on it. These facts are addressed with supporting exhibits at Paragraph 61 of our Counter-Memorial.

The heparin scandal and the expansion of globally produced products in the United States occurred at about the same time that the U.S. Congress's investigative arm, the General Accountability Office, or GAO, was investigating FDA. You heard mention of the GAO during Dr. Rosa's testimony at transcript Page 1078, and we've included several GAO reports in the record at Exhibits R-15, R-17, R-18, R-29, R-30, R-49, R-50, and R-68. GAO found that between 2002 and 2007, FDA annually inspected only about 8 percent of foreign drug manufacturing facilities. And at that rate, it would take 13 years to inspect each one. That's in Exhibit R-18 at Page 23.

15:02:05 Recognizing the risks this presented, in 2009 the GAO placed "protecting the public health through enhanced oversight of medical products" on its high-risk list, making it among the 30 most urgent priorities across the entire United States Government. For that I would refer you to Exhibit R-30 at Page 15.

So this is the context for the 2009 speech by Dr. Margaret Hamburg that Apotex relies upon so heavily. In the speech, which is at Exhibit C-51, Dr. Hamburg noted the "steep decline in the FDA's enforcement activity over the past several years" and sought a return to enforcement levels that FDA had met previously. But there were also stark reminders of the other side of FDA's delicate regulatory balancing equation: Ensuring that medically necessary drugs are not in shortage.

As FDA reported to Congress, "Drug shortages have risen steadily from 2005 and hit an all-time high of 251 drug shortages in 2011." In its response to Congress, which is in the record at R-452, FDA noted that more than half of the drug shortages were related to manufacturing problems. So risk of adulterated

15:03:23 drugs on the one hand and drug shortages on the other. And it is between this Scylla and Charybdis that the FDA is forced to operate every day.

Now, in light of the challenges of globalization, the heparin scare, and the GAO Report, FDA took several actions. It increased the number of foreign inspections undertaken each year. It quadrupled funding for foreign inspections. It increased the number of foreign inspectors and created a Dedicated Foreign Drug Cadre of experienced investigators for the task. And FDA increased the number of Warning Letters for cGMP violations, which indicated less tolerance for those violations. And, finally, coincident with the increase in inspections, FDA also increased enforcement actions after 2009, including detentions and refusals for products manufactured outside the United States.

As we previously mentioned, Apotex's assertion that this situation is unique--that its situation is unique does not withstand scrutiny. In fact, drugs from 41 facilities, including Apotex's, were added to the Import Alert between 2009 and 2011.

15:04:32 Apotex itself understood this in 2009. During the Signet inspection, Apotex's head of quality assurance sent an e-mail to Jeremy Desai explaining some of FDA's significant cGMP findings. He wrote--this is Exhibit C-58--"Interesting general comments that the focus of GMP and the strong stance taken on issues is not simply a reaction to the Warning Letter or singling out Apotex. This is a new yardstick that FDA appears committed to using on everyone."

And I would just pause here to note for the Tribunal that the record bears this out. At Exhibit R-244 is a chart setting forth all of the instances where FDA put a firm on Import Alert, either concurrent with or before a Warning Letter was issued.

In short, these changes were not political. They were not unique to Apotex. They were necessary to adapt to the globalized economy in pharmaceutical manufacturing. Critically, however, the underlying laws on which enforcement is based have not changed--or least had not changed at the time of the events relevant here.

Apotex, nonetheless, continues to insist that

15:05:40 it was the victim of a new politically motivated enforcement policy, that Edwin Rivera-Martinez targeted Apotex and placed Kristi Zielny on an inspection to put Apotex on the Import Alert. According to Apotex, as Mr. Hay put it this morning at Page 1613 of the rough transcript, the Signet inspection was "not conducted for purposes of identifying deviations or corrections; rather, its purpose was to identify cGMP deviations to support an Import Alert."

The record of this case, even after extensive discovery and seven hours of cross-examination, does not support Apotex's theory. And I'll give you three examples. First, for all the talk about Mr. Martinez, he's the very person who recognized the need to hold off putting Apotex on the Import Alert pending a drug shortage analysis. That's Exhibit C-502, which is in the slides.

Similarly, Mr. Hay this morning at transcript 1611 and Slides 10 and 11 showed you Document C-359, the e-mail from Ms. Woodcock and then Ms. Autor as proof that FDA was moving forward with the Import

15:06:49 Alert in June of 2009. We submit this e-mail proves the opposite. If you move to the top e-mail on that chain, you'll see FDA holding off on an Import Alert against Apotex in order to conduct a drug shortage analysis. But if you look at Ms. Woodcock's e-mail, you will see another key point. She says that Apotex is a "great illustration of why generics need QBD"--which means quality by design. She goes on to say, "Their QC unit has no idea what is going on and not sure root cause will help here."

Now notwithstanding this realization, FDA did not rush to action. They met with the company and inspected another of its facilities to verify whether the Agency's suspicions were correct, which, of course, they turned out to be.

Second, although Apotex is quick to criticize Ms. Zielny's presence on the inspection, it bears recalling that it was Mr. Payne, not Ms. Zielny, who ultimately recommended OAI for Signet. And it was Mr. Payne's supervisor from ORA who approved of forwarding that recommendation to CDER. Ms. Cate showed you these documents last week at Page 1354 of

15:07:53 the transcript.

Third, Apotex continues to insist that the Import Alert was preordained in August 2009, despite Mr. Payne's lengthy testimony about the conference call with numerous individuals to discuss pre-approval inspections for Apotex's many pending ANDAs. Apotex has yet to explain why FDA would have done this, if an Import Alert was a foregone conclusion before the Signet inspection. It has no answer because the Import Alert was not, in fact, preordained at all.

I would also like to comment on the assertion this morning that Ms. Zielny was already identifying observations before the Signet inspection began. This is at Page 1613 of this morning's transcript, and it is in reference to Exhibit C-507.

Now, Apotex highlighted the bottom sentence for you, but it's important to read the entire message. What Ms. Zielny is referring to in that e-mail is her pre-inspection research into Field Alert Reports for the Signet site. Now, FDA can obviously tell whether a Field Alert was late from the face of the Report itself, which was already in FDA's

15:08:55 possession before the inspection began. Here, Ms. Zielny is pointing out that Signet has been filing reports late. And this is, of course, precisely the same problem that led to Etobicoke Warning Letter, yet Apotex still has not fixed it several months later.

It was also suggested this morning--this is at Pages 1611-1612 of the transcript--that the concerns expressed in FDA's Etobicoke Warning Letter concerning batch failure investigations were disingenuous because FDA did not ask Apotex for copies of all the batch failure investigations at the close of that inspection.

I would just remind the Tribunal what Ms. Emerson said on this general point in Paragraph 23 of her First Witness Statement. When she asked Apotex during the Etobicoke inspection why Apotex was having so many batch failures, the Response was that "as a generic company, they do not perform R&D." Now, Ms. Emerson goes on to say she was floored by that statement, and so it's understandable why FDA was also concerned and why this issue made its way to the Etobicoke Warning Letter.

15:09:58 Finally, I would like to address the assertion that the fact that Apotex was repeatedly failing to follow cGMP regulations somehow was not important to the Agency's Import Alert determination, since repeat violations was not prominent in the Key Issues Document, which is Exhibit C-358, the Etobicoke Warning Letter, which is Exhibit C-41, or the Import Alert letter recommendation memo, which is Exhibit C-64.

I would just remind the Tribunal how prevalent this issue of repeat violations is in the record of this case. Apotex had repeat violations in several areas, including batch failure investigation, contamination procedures, and Field Alert Reports, to cite a few examples. The fact that the Import Alert recommendation memo on Page 2 stressed other issues such as Apotex's "lack of adequate process controls" that raised "serious concerns regarding the firm's quality and production systems" does not change the facts that Apotex had a string of repeat violations at these facilities.

The evidence in the record plainly

15:11:03 demonstrates that throughout the period between the Etobicoke and Signet inspections, FDA personnel became increasingly alarmed about the situation at Apotex. Documents evidencing this growing level of alarm are cited in Paragraphs 82 and 83 of our Counter-Memorial and Paragraphs 45 to 52 of our Rejoinder.

FDA considered an Import Alert as early as April 2009, but held off. And the Signet inspection then uncovered actual and significant cGMP violations. These violations were admitted by Apotex and, more importantly, confirmed by Health Canada and Apotex's own third-party consultants.

So without conceding the truth of the argument, what Apotex's argument appears to be or what it boils down to is that FDA was zealous in targeting Apotex. Zealousness borne out of the suspicion that Apotex had significant cGMP problems. But the Signet inspection confirmed that suspicion, uncovering numerous undisputed cGMP violations, and under well-established law, FDA responded appropriately. It is far from being improper. This is exactly the response that trained, conscientious regulators should

15:12:11 have with regard to the public health.

Now, I'd like to pause here to address Apotex's contention about the Witnesses that appeared in this arbitration and the Witnesses that did not.

The United States provided the Witnesses who had the most information about the relevant issues as presented in Apotex's Memorial: Carmelo Rosa, Debra Emerson, Lloyd Payne, and Michael Goga. Dr. Woodcock and Debra Autor and Mr. Friedman were certainly involved in the decision to put Apotex on the Import Alert, but they were not involved in the day-to-day process or in the communications between FDA and Apotex. And, furthermore, they could not have opined on many of the issues for which Apotex claims Dr. Rosa's testimony is deficient. The drug shortage analysis is one example.

And on this point, we know that Dr. Rosa stated unequivocally that drug shortage analyses occur in every case, including this one. Apotex has provided no reason to doubt that testimony, which is at Page 884 of the transcript.

Now, Apotex also denied this morning that the

15:13:09 actions taken by other regulatory agencies around the world confirmed the appropriateness of FDA's actions. Apotex cited only the public releases by those agencies, and this is at Pages 1618-1619 of this morning's transcript and Slides 27 to 30.

But counsel did not address the e-mail exchanges between these agencies and Apotex, or contemporaneous internal Apotex e-mails, which paint a much different picture. For example, the e-mail in which Apotex's Bruce Clark reported to his superiors a conversation with Medsafe, the New Zealand agency, in which Medsafe representatives told Mr. Clark that if Apotex were a New Zealand company, "they would have shut them down." That's Exhibit C-99.

All these e-mails, which show the grave concern shared by the other regulatory agencies, are discussed in the Counter-Memorial at 66-71--that is, Page 66-71.

More importantly, Apotex fails to mention that all of these countries--Australia, New Zealand, and the European Union--were in Mutual Recognition Agreement with Canada; they were thus bound by

15:14:17 Health Canada's compliance ratings. They also benefited from monthly calls with Health Canada throughout 2010, specifically for Health Canada to update its agreement partners on Apotex's remediation. The United States is not a Party to that Agreement.

The fact of the matter is that FDA's actions in this case were necessary. Apotex was not in control of its processes, and this put the quality of its drugs into question. And absent FDA's actions, it was not clear when this issue would have ever gotten resolved.

Now, in this respect, I would like to point the Tribunal to the First Witness Statement of Edmund Carey. Mr. Carey, Apotex's current Director of Corporate Compliance, stated at Paragraph 52 of his statement "Although Apotex would have engaged into an enhancement program, in any event, to consolidate compliance with cGMP, the timing and allocation of resources would have been different if Apotex's facilities at Etobicoke and Signet had not been placed on Import Alert. FDA's actions prompted the organization to allocate intensive time and resources

15:15:15 to demonstrate compliance and systems improvements."

Mr. President, Members of the Tribunal, this paragraph from Mr. Carey's Witness Statement speaks volumes. Apotex itself recognized that it was not cGMP compliant at Etobicoke and Signet. It admits that it had not given cGMP a priority but for the Import Alert. Resources would have been allocated to other areas.

Now, from FDA's perspective, this was precisely the problem, and it could not sit idly by while Apotex prioritized other projects over the quality of the drugs and the safety of the U.S. consumers. As Mr. Vodra colorfully put it at the close of his testimony, "companies frequently do not hear FDA clearly until FDA's basically hits them alongside the head with a two by four." That's from the transcript at the Page 1175. Mr. Carey's Statement in this arbitration makes clear that Apotex might have been one of those companies.

FDA's actions against Apotex were legally permissible. They were appropriate. And as Mr. Carey's e-mail demonstrates rather clearly, FDA's

15:16:15 actions were necessary under the circumstances.

Mr. President, Members of the Tribunal, if there are no questions, I would ask that you call on my colleague, Ms. Grosh, who will respond to the Tribunal's questions posed on Saturday.

PRESIDENT VEEDER: Thank you.

MS. GROSH: Thank you, Mr. President.

Mr. President, Members of the Tribunal, I would like to address the questions posed by the Tribunal in its November 23 e-mail to the Parties.

The Tribunal first asked whether the Parties agree that res judicata operates as part of a jurisdictional objection in the present case given that res judicata is not by itself usually an issue of jurisdiction.

The United States raised the preclusive effect of the Apotex I and II Award as a jurisdictional objection in our Rejoinder. In our view, the defense of res judicata is properly a jurisdictional objection here because the prior Tribunal dismissed Apotex's claims for lack of jurisdiction.

15:20:20 Specifically, the prior Tribunal determined that Apotex Inc. did not qualify as an investor who has made an investment in the United States for the purposes of NAFTA Articles 1116 and 1139. And the Tribunal dismissed Apotex's claims in their entirety on the basis that "the Tribunal lacks jurisdiction in relation thereto."

That's at Paragraph 358(a) of the Award.

The Apotex I and II Award precludes relitigation of the threshold jurisdictional question of whether Apotex Inc. and its privy, Apotex Holdings, qualifies as an investor with an investment in its ANDAs. The application of res judicata would mean that this Tribunal also lacks jurisdiction over Apotex Inc. and Apotex Holdings as investors by virtue of the ANDAs.

Notably, the Waste Management II Tribunal dealt with res judicata as a jurisdictional objection. In its Decision on Mexico's preliminary objection concerning the previous proceedings, the Tribunal chaired by Professor James Crawford, referred to Mexico's objection based on the alleged res judicata

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15:21:37 effect of the previous proceedings as an Objection to Jurisdiction.

The decision states, in part, "An exchange of views took place on the venue of the arbitration and on the procedure for dealing with the Respondent's objections to jurisdiction based on the previous proceedings, and in particular on the decision of the previous Tribunal."

The Waste Management II Tribunal's final Award detailed the procedural history of the jurisdictional phase making clear that Mexico's objection was treated in a separate jurisdictional phase of those proceedings. Now, I would note that the Final Award is not in the record, but if it would help the Tribunal, we would be happy to provide a copy.

Finally, we refer the Tribunal Paragraph 68 of the ILA Final Report on Res Judicata and Arbitration, which suggests that preclusive effects of prior Arbitral Awards may go to jurisdiction or admissibility. But the question is somewhat moot as a preclusion defense is to be raised early in the

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15:22:43 proceedings. Of course, if the Apotex I and II Award had been rendered earlier, the United States would have sought bifurcation also on the basis of the res judicata effect of that Award.

The Tribunal has also asked the Parties for their views with respect to whether, if the case of Apotex Inc. is affected by res judicata in these proceedings, the position of Apotex Holdings Inc. is also affected by res judicata.

In this connection, the Tribunal referred to Claimants' submission in the transcript at D3.542 and on D3.544. The Claimants acknowledge that "Apotex I and II is binding between the Parties to that case and to privies to those Parties, and we would accept that Apotex Holdings is one of those privies."

Apotex has argued that res judicata can only apply to the particular case, and that is Apotex I and II. We've already explained why this argument fails. But, critically, Apotex's acknowledgment last Wednesday necessarily means that where Apotex Inc. is affected by res judicata in these proceedings, Apotex Holdings must also be affected as one of its privies.

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15:24:05 So, in our view, this must be deemed now to be a matter of common ground between the Parties.

The Tribunal observed that the Respondent in Apotex I and II is identified on the Award as the Government of the United States, not the United States itself. We agree with the Claimant that the Respondent for both cases is, in effect, the United States.

The Tribunal has noted that the Parties appear to disagree as to the res judicata effect of the reasons for an Award and requested further legal guidance from the Parties as to two questions: Namely, one, whether it is permissible for the second Tribunal to consider the first Tribunal's reasons for its decision in the latter's operative part, where those reasons are not expressly set out but are implied in the operative part; and, two, if a reason is only implied in the operative part, where that reason is or may be unnecessary for the decision.

Now, as to the first part of the Tribunal's question, our view is that it is clearly permissible for this Tribunal to consider the reasons for the

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15:25:18 Apotex I and II Tribunal's decision where those reasons are not expressly set out in the operative part.

The res judicata effect of such reasons is now well established internationally. As the ICJ stated in Paragraphs 125-126 of the Genocide case, "In the view of the Court, if any question arises as to the scope of res judicata attaching to a judgment, it must be determined in each case having regard to the context in which the judgment was given...

"For this purpose, in respect of a particular judgment, it may be necessary to distinguish between, first, the issues which have been decided with force of res judicata, or which are necessarily entailed in the decision of those issues; secondly, any peripheral or subsidiary matters, or obiter dicta; and, finally, matters which have not been ruled upon at all. Thus, an application for interpretation of a judgment under Article 60 of the Statute may well require the Court to settle a difference of opinion between the Parties as to whether a particular point has or has not been decided with binding force. If a matter has not in

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15:26:36 fact been determined, expressly or by necessary implication, then no force of res judicata attaches to it; and a general finding may have to be read in context in order to ascertain whether a particular matter is or is not contained in it."

Recent Awards rendered by the Iran-U.S. Claims Tribunal in State-to-State claims also establish that the reasons provided in a decision also have res judicata effect to the extent that those reasons are relevant to the actual decision on the question at issue.

In the Award in Case Number A/33, the Tribunal citing the Orinoco and the Pious Fund cases held that the reasons the Tribunal provided in its decisions in Case Number A28, too, have binding force as between the Parties to the extent that those reasons are relevant to the actual decision on the question at issue. Every matter and point distinctly in issue in a judgment by an international court or Tribunal which was directly passed upon and determined therein and which was its ground and basis is precluded by said judgment and, accordingly, has

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15:27:52 binding force.

Members of the Tribunal, this decision is also not in the record, but if it would be helpful, we can provide copies.

The Tribunal here also has asked the Parties to take note of the scope of res judicata as applied by non-common law Tribunals including certain cases from the European Court of Justice of which a majority of justices are from civil law systems. In our view, these cases, together with the Genocide case and the example I've just cited from the Iran-U.S. Claims Tribunal, confirm the broad scope of res judicata as applied by international and non-common law tribunals. Reasons are given res judicata effect where those reasons are relevant to the decision contained in the operative part.

As to the second part of the Tribunal's question, these Authorities provide that reasons will be given res judicata effect where they are relevant to the decision in the operative part. Peripheral or subsidiary matters, or obiter dicta, and matters which have not been ruled upon at all are not given

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15:29:06 res judicata effect. A similar approach was taken by the Amco versus Indonesia Tribunal in the resubmitted case, and the language is up on the slide.

And as explained by the Genocide case, an issue not expressly determined may still be determined by necessary implication. And let me explain how this applies to Apotex's argument that the previous proceedings dealt with tentatively approved ANDAs while these proceedings deal with finally approved ANDAs.

Last week we pointed to the record of the previous proceedings and demonstrated that the approval status of Apotex Inc.'s ANDAs was an issue that was fully and actually litigated and determined. The Apotex I and II Tribunal considered the approval status of the ANDAs in determining whether the ANDAs could constitute investments under Article 1139.

Ultimately, the Tribunal found at Paragraph 224 of its Decision that "the jurisdictional issue here turns upon the inherent nature of the relevant ANDAs, not the nature of Apotex's rights over them. As set out above, even assuming that the ANDAs

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15:30:22 were Apotex's exclusive property, they remained no more than application for permission to, in this case, export and, as such, neither fell within NAFTA Article 1139(g), nor constituted investments as contemplated more generally by NAFTA Chapter 11."

Thus, the Tribunal found that even when viewed as exclusive property of Apotex Inc., as Apotex now argues, finally approved ANDAs are--by their inherent nature, ANDAs are no more than applications for revocable permission to export generic drugs to the United States.

As a matter of logical construction, Apotex Inc.'s finally approved ANDAs cannot possess any qualities that would change their inherent nature. Apotex Inc.'s approved ANDAs are still no more than applications for revocable permission to export generic drugs. So the Apotex I and II Tribunal determined by necessary implication that finally approved ANDAs cannot be investments for purposes of Article 1139. If this Tribunal were to come to a different conclusion, it would necessarily contradict the conclusions of the previous Tribunal on the

15:31:42 inherent nature of the ANDA.

With respect to the second part of the Tribunal's question, the Tribunal also asked whether res judicata would operate as regards a pure issue of law decided in the first Award, such as the decision on the legal burden of proof regarding the obvious futility exception.

The United States does not believe that for present purposes it would be necessary or useful to consider whether res judicata may operate as regards a pure issue of law. In Apotex I and II, both Parties accepted that judicial finality must first be reached in the host State's domestic courts unless such recourse is obviously futile. That was at Paragraph 257 of the Award.

Accordingly, there is no reason to permit Apotex to switch its position simply because its litigation interests have changed from its earlier case to this one.

The Tribunal also asked the Parties whether they have submitted by special agreement to an equivalent form of res judicata given the combined

15:32:52 effect of Article 32(3) and 32(2) of the 1976 UNCITRAL Arbitration Rules, which governed the previous proceeding.

NAFTA Article 1120 provides that a disputing investor may submit a claim to arbitration under the ICSID Convention, the ICSID Additional Facility Rules, or the UNCITRAL Arbitration Rules. The rules chosen by the investor govern the arbitration except to the extent modified by Section B of Chapter 11. In the previous arbitration, Apotex Inc. chose to submit its claims under the 1976 UNCITRAL Rules. Article 32(2) of those rules provides that the Award is final and binding on the Parties, and Article 32(3) provides that the Award is to include the reasons upon which the Award is based.

As we argued last week, we consider that the combined effect of these provisions means that the reasons for an Award may also have final and binding or res judicata effect as between the Parties. Further, the combined effect of the provisions logically suggests not only the dispute but also the issues actually determined in that dispute are

15:34:13 res judicata. This is because the purpose of an Award is to decide the Parties' dispute for all time, both as to the whole and as to its constituent parts.

Article 1136(1) does not operate to modify the UNCITRAL Rules or their effect, as Apotex counsel suggests. Counsel for Apotex also refers to Article 1131(1), which requires the Tribunal to decide the issues in accordance with the NAFTA and applicable rules of international law. Our position on this issue is fully consistent with international law on the scope of res judicata as demonstrated by the Authorities we've cited.

Finally, with respect to res judicata, the Tribunal asked whether the legal place or the seat of the first arbitration and the Apotex I and II Award, as expressed in that Award to be New York, was relevant the Parties' case on res judicata in this arbitration.

The United States observes two points in this respect. First, as we noted in our Rejoinder--and this was at note 235--Apotex Inc. declined to set aside of the Award within the time permitted by the

15:35:32 law of New York, as the place of arbitration. There is no dispute that the Apotex I and II Award is final and binding and capable of recognition in New York. In this connection, we refer the Tribunal to the ILA Final Report on Res Judicata and Arbitration.

Paragraph 29 of that Report states that "to have conclusive and preclusive effects: The prior Award must be final and binding and capable of recognition in the country where the Arbitral Tribunal of the subsequent arbitration proceedings has its seat."

Second, although not directly applicable, U.S. law, including the law of New York, recognizes and applies res judicata and issue estoppel, as we explained in Paragraph 104 of our Rejoinder, citing various Authorities.

Moreover, since at least 1982, New York courts have held that res judicata, including issue estoppel, applies to arbitration Awards and may preclude relitigation, not only of a claim, but of specific issues. Again, we can refer the Tribunal to Authorities not in the record on this point. Those

15:36:47 are posted on the screen.

Mr. President, Members of the Tribunal, I would now like to turn to your questions regarding Sandoz/Novartis and Teva as regards Claimants' Article 1102 and 1103 claims. I won't revisit the three-step analysis required for establishing a National Treatment or Most-Favored-Nation Treatment violation. Instead, I would like to address whether Apotex has established that it was accorded less favorable treatment in like circumstances than Sandoz/Novartis and Teva on the basis of Apotex's Canadian nationality of ownership.

In response to this inquiry, I will first touch upon three of the issues raised by Apotex this morning: Nationality-based discrimination, burden of proof, and documents and discovery. Then I will touch upon three areas regarding the comparators the Tribunal invited the Parties to focus on.

First, Apotex criticizes the United States' but-for test for determining whether there has been discrimination on the basis of nationality of ownership under Articles 1102 and 1103. That test was

15:38:11 offered in response to Apotex's continued failure to provide the Tribunal with a methodology that can even demonstrate discrimination on the basis of nationality of ownership.

Instead--indeed, Apotex did not address discrimination on the basis of nationality of ownership during its presentation. The United States's methodology is not new and was attributed for example to the United States by the Methanex Tribunal at Paragraphs 14-16 of Part 4, Chapter 5, of the Methanex Final Award. And that was submitted at CLA-34.

The Methanex Tribunal rightly sought in that case to isolate the factor of nationality in its "like circumstances" analysis. In its discussion of Pope & Talbot in Paragraph 19, the Methanex Tribunal stated that that Tribunal selected entities that were in the most like circumstances and not comparators that were in less like circumstances. And then acknowledged that it would be a forced application of Article 1102 if a Tribunal were to ignore the identical comparator and to try to lever in an, at

15:39:30 best, approximate and arguably inappropriate comparator. This is not a new test, but it is the one that Apotex cannot satisfy.

Second, Apotex continues to try to shift the burden of proof to the United States. The UPS Tribunal, however, made clear that failure by the investor to establish any one of the three elements in a National Treatment analysis will be fatal to its case. This is a legal burden that rests squarely with the Claimant. That burden never shifts to that Party.

Contrary to Apotex's point this morning, the UPS Tribunal was concerned with nationality-based discrimination which is clear in its conclusion that UPS Canada is not in like circumstances to Canada Post in respect of its program, and indeed, essentially for the same reasons, is not accorded less favorable treatment than Canada Post or treated differently because of nationality.

Apotex understandably otherwise ignores the UPS Award. Apotex now points the Tribunal to Feldman versus Mexico in an attempt to find support for its efforts to shift the burden to the United States. But

15:40:51 that case provides no support for Apotex. There, the Feldman Tribunal observed in a much less complicated case that while no cigarette reseller/exporter could legally have qualified for certain tax rebates, at least three Mexican-owned cigarette reseller/exporters were granted them.

The Tribunal noted that: There is evidence of a nexus between the discrimination and the Claimant's status as a foreign investor. In the first place, there does not appear to be any rational justification in the record for Mexico's less favorable de facto treatment of Claimant entity Semsa other than the obvious fact that Semsa was owned by a very outspoken foreigner who had, prior to the initiation of the audit, filed a NAFTA Chapter 11 claim against the Government of Mexico.

This case, as you've heard for the past week and can see in the submissions, is not as simple as Mexican-owned investments in Mexico get rebates and U.S.-owned investments in Mexico do not get rebates. There is no evidence of a nexus between the alleged discrimination and Apotex's alleged status as a

15:42:08 foreign investor.

And, lastly, the United States has provided evidence supporting FDA's exercise of enforcement discretion in the complicated matters of public health at issue in this case.

And this evidence leads me to my third point. Again, Apotex is crying foul on documents and discovery, but as the United States explained in its letters of October 29 and November 6 regarding Apotex's request to exclude relevant evidence, Apotex's claims are not persuasive. The United States spent over $200,000 on an outside vendor to assist it in responding to Apotex's numerous document requests. Apotex could have formulated appropriate requests for documents rather than the overbroad request Apotex actually made.

Apotex also could have availed themselves of the United States's standing offer in its March 20 letter to the Tribunal to consider requests for additional specific individual documents from Apotex after it has reviewed the produced documents. Apotex, moreover, was given an additional opportunity to

15:43:26 supplement its Reply, but it opted not discuss documents reflecting the relevant circumstances in that submission either. The United States should not be penalized for Claimants' failure to do so.

In crying foul and asserting that the burden should shift to the United States, Apotex is again trying to have it both ways. As we've seen throughout the hearing, Apotex wanted all fact presentations in this hearing to be closed to the public, yet at the same time, Apotex states that the United States should provide third-Party documentation, documentation regarding its competitors. The United States's position on third-party information is consistent with Apotex's position regarding its own proprietary information.

In addition, the documents that the United States could produce, such as Form 483s and Establishment Inspection Reports, continue to be minimized by Apotex before the Tribunal. Once again this morning, Apotex asserted that the Tribunal need look no further than Warning Letters. But I won't belabor this point further.

15:44:36 Because of the limitations on third-party information, the United States, too, has had to rely on public sources of information and Witness testimony, with one exception. Other than the third-party documents provided to the United States that were responsive to Apotex's search terms and form--and from a set of documents that were agreed upon by the Parties.

I will now turn to this evidence to discuss three areas regarding the comparators that the Tribunal asked us to address: One, Sandoz and Teva's voluntary responses to FDA's cGMP findings; two, the medical necessity and short supply of products from Sandoz and Teva's facilities, and; three, Sandoz and Teva's U.S.-based manufacturing.

PRESIDENT VEEDER: Just pausing there. If you think we should go into closed session at any time--this applies to the Claimants as well--please tell us.

MS. GROSH: Okay. Let me confer for a second.

(Pause.)

15:45:52 MS. GROSH: I don't think there is anything here that would require us to go into closed session.

PRESIDENT VEEDER: Thank you. We will remain in open session.

MS. GROSH: I will conclude by showing that Apotex cannot establish that it was sufficiently like Sandoz and Teva or that it was accorded less favorable treatment on the basis of its Canadian nationality.

First, I'll briefly discuss the voluntary responses to FDA's findings of cGMP deficiencies at the facilities at issue, including the Teva Jerusalem and Sandoz Canada Boucherville facilities.

As shown in our submissions and discussed in testimony last week, Apotex's responses contrast significantly with those from Sandoz and Teva. It is important to recall that Apotex did not contemporaneously dispute FDA's cGMP determinations. In fact, Apotex's third-party consultants confirmed FDA's determinations for all six quality systems which were shared between the Etobicoke and Signet facilities. Yet, Apotex declined to cease production or limit distribution beyond one or two drugs from

those facilities. Instead, Apotex offered what it called "a goodwill gesture" which did not adequately address FDA's concerns.

And this contrasts with Apotex's voluntary response to Health Canada when Health Canada found that Apotex was commingling toxic and nontoxic material at Signet, Apotex responded by committing to cease manufacturing any cytotoxic products at Signet.

This action permitted Health Canada to record this observation in the second highest rather than the highest risk category, which would have resulted in a noncompliant rating, potentially costing Apotex its establishment license.

Apotex's voluntary response to FDA also contrasts starkly with the voluntary responses of Sandoz/Novartis and Teva. Novartis limited production at Sandoz Inc.'s Colorado and North Carolina facilities, and at Sandoz Canada's Boucherville, Québec, facility.

Novartis informed its Shareholders and the public that "Sandoz also continued to strengthen quality operations across its manufacturing network.

This includes its three North American sites where the division is on track to meet its remediation commitments. Sandoz has upgraded senior leadership in quality and manufacturing operations, both globally and the at site level, and is further strengthening organizational capabilities, facilities, and systems. While Sandoz slowed down production to implement remediation activities at its three North American sites, delivery performance across all sites has improved. Further improvements in service levels and output are expected as remediation progresses."

Further, as The Globe and Mail reported, Sandoz Canada said it was intensifying efforts to ensure high quality standards and stood behind the safety and efficacy of its products, none of which have been recalled. It said the decision to halt production was voluntary and related to efforts to restore high quality standards in manufacturing operations and said it had no plans to close the Boucherville plant. Sandoz did not respond to questions about how the problems developed or why they weren't dealt with to the FDA's satisfaction after

they were first identified.

"In total, Sandoz said it had committed a total of over $170 million to improve quality at the Boucherville plant as well as two other plants in Colorado and North Carolina that were also cited in the FDA letter. Sandoz said those 'remediation' efforts were already under way when it received the FDA letter."

MS. GROSH: Can I make a request of the Tribunal?

(Discussion off microphone.)

MS. GROSH: Sorry for the interruption.

PRESIDENT VEEDER: My apologies to you.

MS. GROSH: Teva also undertook more significant voluntary action than Apotex had. As reflected in FDA's letter to Congress on sterile injectable shortages, which is at Exhibit C-452, there were multiple reports of serious injury and illness related to the use of Teva's propofol injectable product that prompted an inspection in July of 2009 and recalls of the affected product. While FDA was monitoring Teva Parenteral's Irvine, California,

facility and weighing the risks of those products against their nonavailability, Teva voluntarily shut that facility down in April 2010.

As set forth in a recent Teva Securities filing--this was submitted at R-215--"In December 2009, the FDA issued a Warning Letter related to our Irvine, California, injectable products manufacturing facility. We voluntarily ceased production at the facility during the second quarter of 2010 and executed a remediation plan required by the FDA. In April 2011, we resumed limited manufacturing activity. We have been working closely with the FDA and are gradually releasing more products for distribution. On October 23, 2012, we received a letter from the FDA acknowledging that our Corrective Actions addressed the violations noted in the December 2009 Warning Letter."

The Teva shutdown also is reflected in the CDER briefing agenda at Exhibit C-572, as follows: In 2010, the firm decided to simply shut down production at the Teva Parenteral medicines facility in Irvine, causing massive shortages, market supply distribution

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of products that are medically necessary for patients. When FDA issued a Warning Letter to Teva Pharmaceutical's Jerusalem facility 13 months later, Teva again offered to cease production, which caused concern and confusion among some at FDA.

You will recall Dr. Rosa's testimony concerning his personal conversation with the head of Teva's compliance and her intention to shut the factory down completely. After FDA's entreaty to continue shipping medically necessary drugs, Teva limited distribution of products from that facility for remediation.

Now, in this regard, I would like to address a point that Apotex raised this morning. Apotex asserted that the FDA told Teva to shut down the Jerusalem facility. But the full sentence partially quoted by Apotex makes clear that Teva already knew about the importance of a possible shutdown, as Teva Parenteral had done just this. That sentence reads in full at Exhibit C-424 and, "Mr. Cruz acknowledged that the shutdown of the Irvine facility is the type of corporate" FDA--I'm sorry; corporate "reaction FDA is

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looking for when the firm is not in substantial compliance and asked if Teva plans to take the same strategy for other facilities when they are found to be noncompliant."

ARBITRATOR ROWLEY: Can you just identify who Mr. Cruz is?

MS. GROSH: Perhaps we can get that information at the end.

Overall, Apotex's gesture of goodwill recall pales in comparison to Sandoz and Teva's voluntary actions, which included ceasing and limiting production as well as distribution. Apotex's voluntary action is in no way like that of Sandoz and Teva.

Let me turn to the second topic; that is, medical necessity and short supply of drugs. As discussed last week, before adopting the Import Alert for Etobicoke and Signet, FDA determined that Apotex did not produce any medically necessary or short supply drugs with a single exception. FDA further determined that adoption of the Import Alert with respect to Etobicoke and Signet would not create any

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sustained shortages. Sandoz Canada, by contrast, voluntarily limited its production for the U.S. market to sterile injectables, in particular, lifesaving single-source drugs, with the concurrence of FDA's drug shortage office.

The United States has introduced a number of documents making clear that sterile injectables have been in chronic short supply in the United States market. Apotex's Reply highlighted one such drug, acknowledging that the circumstances surrounding Sandoz Canada involved medical necessity and stating that "in order to prevent a shortage in May 2012, FDA allowed Sandoz Canada to import into the United States phentolamine mesylate, a drug manufactured at Boucherville but not authorized for sale in the United States."

Apotex also acknowledged that such distribution was temporary, and was abandoned once an alternative supplier became available. Apotex also provided a medically necessary drug, deferiprone, to the United States for compassionate use despite the Import Alert.

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I've already discussed the shortages caused by Teva Parenteral's decision to shut down its Irvine facility. Similarly when cGMP deficiencies were identified at Teva Pharmaceutical's Jerusalem, Israel, facility and Teva offered to shut it down, FDA saw "the need for a teleconference with Teva as soon as possible to let them know the medical need for these and to work with them to keep manufacturing medically necessary drugs at the supply levels needed to meet patient needs while fixing their problem (as long as benefit outweighs any potential risks). We don't see any products on the list that would not be impacting patients, and we are worried about the impact of any supply disruption at the Jerusalem facility. Teva has a very large market share for these products and acquired additional market share when cGMP issues occurred in recent years at other manufacturers making these drugs."

Thus, because Teva's drugs were medically necessary and in short supply, FDA was willing to work with Teva as long as the benefit outweighed any potential risks.

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15:58:34 Finally, I'll briefly discuss U.S.-based manufacturing. Apotex has identified as comparators Sandoz Inc.'s Broomfield, Colorado, and Wilson, North Carolina, facilities. Apotex also identifies as a comparator Teva Parenterals Inc.'s sterile injectable facility in Irvine, California. All three of these facilities are, of course, in the United States.

Apotex's Etobicoke and Signet facilities, by contrast, are not in the United States. Nor do they manufacture sterile injectables. Indeed, Apotex Corp. sells sterile injectables manufactured by third parties, such as Hospira.

Sandoz and Teva's U.S.-based facilities are not subject to the same legal regime that Etobicoke and Signet are subject to. These U.S.-based facilities are not subject to Section 801(a) of the Food, Drug, and Cosmetic Act. Their products cannot be detained without physical examination at the U.S. border. And Import Alerts cannot be adopted with respect to them.

Sandoz's and Teva's U.S.-based facilities, moreover, are subject to unannounced inspections.

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15:59:48 They are also subject to U.S. taxes. Apotex Inc.'s Etobicoke and Signet facilities, by contrast, are not. Apotex, thus, seeks to be treated as if it were a U.S.-based manufacturer, but does not seek to subject itself to unannounced inspections or U.S. taxes.

The UPS versus Canada Tribunal found determinative such differences in legal requirements. The Tribunal concluded that UPS Canada was not in like circumstances with Canada Post and essentially for the same reasons was not accorded less favorable treatment that Canada Post or treated differently because of nationality.

In short, Sandoz Inc.'s and Teva Parenteral's U.S. manufacturing facilities are not appropriate for comparison to Apotex's foreign facilities. For these reasons, Apotex cannot establish that it was sufficiently like Sandoz or Teva or that it was accorded less favorable treatment on the basis of its Canadian nationality. Apotex's Articles 1102 and 1103 claims must, therefore, be rejected.

Finally, Members of the Tribunal, I turn to the Tribunal's Questions C1 and C2 related to

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16:01:11 Article 1105. As the United States has noted, customary international law's Minimum Standard of Treatment has only been incorporated into 1105(1) to the extent that a State has accorded treatment to a covered investment. And with respect to investments, Article 1101(b) limits the scope of Chapter 11 to those investments within the territory of the Party.

The rule asserted by Claimants in Paragraph 469 of the Memorial is that a State must provide procedural safeguards to Aliens and Nationals alike on a nondiscriminatory basis. As the United States has noted previously, the prohibition against nationality-based discrimination does not exist in certain, but not all, rules of international law. I'm sorry--does exist in certain, but not all, rules of international law.

Restrictions against nondiscrimination exist within the framework of rules regarding limited areas, such as expropriation, denial of justice, and failure to provide full protection and security. Other than in limited circumstances, no established rule of customary international law has emerged that generally

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16:02:32 prohibits economic discrimination against Aliens.

Now, I refer to the Tribunal to Paragraphs 373-379 of the United States's Amended Statement of Defense in Methanex, which is at CLA-37.

As the Methanex Tribunal observed in Part 4, Chapter C, Paragraph 25 of its Final Award: As to the question of whether a rule of customary international law provides a State, in the absence of a Treaty obligation, from differentiating in its treatment of Nationals and Aliens, international law is clear. In the absence of a contrary rule of international law binding on the State Parties, whether of conventional or customary origin, a State may differentiate in its treatment of Nationals and Aliens.

As the Methanex Tribunal further observed in that paragraph, "The text of the NAFTA indicates that the State Parties explicitly excluded a rule of nondiscrimination from Article 1105." Because Claimants have not established that any new rule of nondiscrimination exists, their claims fail.

But even assuming that a rule of nondiscrimination existed, the United States has

satisfied it. In other words, a Canadian national who owns a pharmaceutical manufacturing facility in Canada is treated the same as a U.S. national who owns a pharmaceutical manufacturing facility in Canada. U.S. law affords these exporters the same procedural safeguards regardless of nationality.

Additionally, a Canadian national who owns a drug facility in the United States has the same rights regarding access to courts and administrative remedies as a U.S. national who owns a facility in the United States.

Claimants have not established the contrary. We explain this in more detail in our Rejoinder at Paragraphs 218 to 230. Thus, as a factual matter, no discrimination exists in U.S. law on this point. Claimants' allegations fail as both a matter of law and fact. Further, I note the Claimants are effectively asking the Tribunal to declare that States must treat those engaging in cross-border the same as those who have invested in a State's territory. The NAFTA has separate dispute resolution procedures for trade disputes, but customary international law does

not require traders to be treated the same as investors.

Mr. President, unless there are any questions, we may want to break at this point for a short moment so we can shift our...

ARBITRATOR CROOK: One quick question, Counsel.

You referred someplace around the transcript, 1720, to limitations on the United States' ability to disclose third-party information.

Can you elaborate a little bit? Are we talking about statutes here? Regulations? Administrative practices? What exactly is it that impedes you from doing what?

MS. GROSH: There are statute and regulations, Mr. Crook. I think I would like to confer with our colleagues from the FDA to give you, perhaps, a more precise answer.

ARBITRATOR CROOK: Thank you.

PRESIDENT VEEDER: Let's break there. Let's break for 15 minutes and we'll come back at 25 past 4:00.

MS. GROSH: Thank you.

(Brief recess.)

PRESIDENT VEEDER: Let's proceed.

MS. GROSH: Thank you, Mr. President. I would like to address the two questions that were asked by the Tribunal, and then I propose turning over the microphone to my colleague, Mr. Sharpe.

First of all, Mr. Rowley asked about the position of Mr. Cruz. This was in connection with the Teva Parenteral's action. His name is Alonzo Cruz, and he's the FDA District Director for Los Angeles, California, and that's where Teva Parenteral's Irvine facility is located.

Then Mr. Crook's question about the Statutory and Regulatory Framework that prohibit or exempt commercially sensitive information from being disclosed, first of all, the two acts, the Federal--the Food and Drug Administration Act Section 301 prohibits anyone from providing trade secrets, and there are personal criminal sanctions that attach if that information is released. And I would also just note that, because of the statute, the

FDA has not even been in a position to provide that material to State Department colleagues in this case.

And then there is the FOIA, and there are exemptions under the FOIA for confidential commercial information, which is a little bit different from trade secrets information. There are also regulations that we cited in letters to Apotex in connection with the document production, and I'm going to very briefly pass the floor over to my colleague, Ms. Thornton, who can give you a couple of citations to those regulations.

MS. THORNTON: Sure. In case you would like the citations, they are 21 USC Section 331(j); 21 CFR, Section 20.61; 5 USC, Section 552(b)(4); and 21 CFR 20.85.

MS. GROSH: So, with that, if there are no further questions, I'd like to turn our presentation over to Mr. Sharpe.

PRESIDENT VEEDER: Thank you. Mr. Sharpe.

MR. SHARPE: Good afternoon, Mr. President and Members of the Tribunal.

I am playing cleanup this afternoon. I don't

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16:27:08 have any slides as I'll principally be responding to some points that were made earlier by the Claimants. Ms. McLeod stated during her opening statements last Monday that Apotex's claims on Jurisdiction and the Merits raised troubling implications for the NAFTA Parties. Apotex's arguments over the past week have exacerbated our concerns. I'll touch on a few of them this afternoon.

The first concern that Ms. McLeod identified is that Apotex's claims seek to expand NAFTA jurisdiction far beyond anything the NAFTA Parties contemplated when they concluded the Agreement. The NAFTA Parties expressly limited their consent to investment arbitration disputes brought by qualifying investors with covered investments. They did not consent to adjudicate trade-related disputes or to pay trade-related damages in investment arbitration.

Here, in our view, Apotex seeks to recover damages arising from a trade Measure--an Import Alert--that was addressed to two of Apotex's Canadian manufacturing facilities. That is wholly improper. Apotex Inc. is an exporter of generic drugs. It has

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16:28:29 made no investments in the territory of the United States. The only investment that Apotex Inc. claims in this arbitration are its ANDAs, and as the Apotex I and II Tribunal correctly concluded, ANDAs are not investments in the United States for purposes of Chapter 11. Whether unapproved, tentatively approved or finally approved, ANDAs are nothing more than applications for revocable permission to export products to the United States. All of the resources that go into the ANDAs themselves merely facilitate cross-border trade, and as such, ANDAs are neither intangible property for purposes of Article 1139(g), nor interest arising from the commitment of capital or other resources for purposes of Article 1139(h).

Apotex this morning again suggested that ANDAs are equivalent to trademarks, but as we made clear last week, this is not correct. Patents, copyrights, and trademarks have long been recognized as property in the United States. And Chapter 17 of the NAFTA expressly obligates the Parties to protect intellectual property such as patents and trademarks. But Apotex has pointed to no evidence that ANDAs are

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16:29:51 recognized as property under U.S. law or that it would be entitled to any property-like remedies under U.S. law such as compensation for the revocation of an ANDA. Apotex Inc.'s ANDAs, even finally approved ones, are never more than applications for revocable permission to export drugs to the United States for resale by others.

Further, freestanding definitions of property divorced from context are not relevant for determining what may be an "investment" for purposes of Article 1139(g). Rather, Article 1139(g) must be understood as a whole, by reference to the objects and purpose of NAFTA Chapter 11. In particular, there's no basis for this Tribunal to give an ANDA status far beyond anything recognized under U.S. law as the law of the host State, nor is there any basis for the Tribunal to accept Apotex's extreme interpretation of Article 1139(h).

None of the three NAFTA Parties accepts that Chapter 11 is meant to protect as investment interests money spent outside the territory of the host State. Indeed, Mexico's non-disputing Party submission has

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16:31:06 expressly asked the Tribunal not to do so in this arbitration.

We heard this morning, once again, Apotex's request that the Tribunal consider the resources that Apotex Holdings has contributed to the United States, including to the U.S. enterprise, Apotex Corp., and to the ANDAs. Those resources would be relevant for determining whether Apotex Holdings is an investor with an investment in the United States, but that point is not disputed. Clearly, Apotex Holdings indirectly owns and controls the U.S. enterprise, Apotex Corp., and indirectly the ANDAs. But what Apotex appears to be asking the Tribunal to do is to treat Apotex Inc. as if it made the same contributions that Apotex Holdings had made, including to Apotex Corp.

But Apotex Inc. has no relationship with Apotex Corp. Apotex Inc. does not own or control Apotex Corp. Thus, the Tribunal must look at which investor made which contributions to the alleged U.S. investments. Here, there is no evidence that Apotex Inc. committed any resources to any investments in the

16:32:17 United States. As the Apotex I and II Tribunal concluded, all of those investments were made in Canada.

Many tribunals constituted under Chapter 11 from Bayview to Grand River have recognized that a principal purpose of Chapter 11 is to protect only those investments made in the territory of the host State. If the Tribunal were to find that an ANDA constituted intangible property or interests arising from the commitment of capital outside the United States, the Tribunal would expose the NAFTA Parties to liability for money damages for investments made outside the territory of the host State.

Apotex has offered no credible argument for this Tribunal to break such new ground here.

Indeed, the Apotex I and II Tribunal carefully considered these arguments after two rounds of briefing and an oral hearing. It rejected them in their entirety as manifestly outside the jurisdiction of Chapter 11. If this Tribunal were to decline to give effect to that Award the Tribunal would be giving Parties, such as Apotex, a free pass to continue

16:33:23 bringing vexatious claims simply by hiring new counsel and dressing up old claims with new arguments. That would disserve the interests of justice and do an end-run around finality of litigation. For Apotex, litigation is a stated part of its business plan. The only way to prevent Apotex from relitigating the same issues is to disallow such claims from proceeding.

In short, for all the reasons we gave during our argument last week and in our submissions, Apotex Inc. is not a qualified investor with covered investments, and its claims should be dismissed. The claims of Apotex Holdings on behalf of the its U.S. enterprise, fare no better. Apotex has acknowledged that it's not enough to have an investment in the territory of the host State in order to claim an investment for purposes of NAFTA Chapter 11. The challenged Measure also must relate to the investor and investment as required by Article 1101(1).

Apotex further acknowledges that, for purposes of Article 1101(1), the challenged Measure must have a legally significant connection to the investor and its investments.

16:34:31 The sole challenged Measure in this case, the Import Alert, did not relate to Apotex Corp., as an investment, or to Apotex Holdings, as an investor with an investment in the United States. To the contrary, as we and Mr. Vodra have made clear, an Import Alert is internal agency guidance. It is neither necessary nor sufficient for the detention of drugs. On its face, it does not create any legal rights or obligations and does not operate to bind FDA or the public. It thus, cannot be said to have any legally significant connection to Apotex Corp. Let me just return to three points I made last week.

ARBITRATOR ROWLEY: Could I just stop you there so I don't lose this? What if we were to conclude that the challenged Measure did operate to bind the FDA just to use your words? Would it, in those circumstances, relate to Holdings? You said it wouldn't relate to Corp. You didn't mentioned Holdings.

MR. SHARPE: I do not believe it would relate to Holdings as an investor with an investment in the territory of the United States. That is, Holdings is

16:36:00 only affected either by a reference to by Apotex Inc. or Apotex Corp. So to the extent that Holdings--to the extent it doesn't relate to Apotex Corp., it doesn't relate to Apotex Holdings as an investor with respect to its investment Apotex Corp.

ARBITRATOR ROWLEY: And if we concluded it did relate to Apotex Corp. or Apotex Inc., would it thus, relate to Apotex Holdings as the owner, direct or indirect, of those entities?

MR. SHARPE: I might give that some thought, Mr. Rowley, if I may.

ARBITRATOR ROWLEY: Perhaps tomorrow even, though it's not Reply. It's a reply to me.

MR. SHARPE: Thank you so much.

PRESIDENT VEEDER: Since you've been interrupted, are you going to deal with the Bellarno case that was cited by the Claimant?

MR. SHARPE: Yes.

PRESIDENT: Thank you.

MR. SHARPE: I'm just about to turn to that in a few moments.

I did want to return to three points I made

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16:36:55 last week just to make those clear. I noted that Apotex Inc.'s sales to Apotex Corp. occur in Canada. That point is evident from Apotex's representations in U.S. and Canadian courts, and the point does not appear to have been disputed this morning. The consequence is that no U.S. Government measure interrupted any transactions between Apotex Inc. and Apotex Corp., contrary to Apotex's arguments throughout these proceedings.

Second, to the extent that Apotex Corp. complains because it could not import drugs from Etobicoke and Signet, the underlying Measure was not the Import Alert. Rather, the Measure was FDA's determination that those facilities were not cGMP compliant; and for that reason, drugs from those facilities were lawfully deemed to be adulterated, could be detained without physical examination and ultimately refused admission into the United States.

Third, the Measure that Apotex points to as showing a legally significant connection to the import alert was actually the Notice of Detention. The regulation Apotex cites states that the Notice of

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16:38:06 Detention needs to be sent to the owner or consignee. The Notice of Detention, thus, would have been sent to any Apotex consignee. Thus, even if there had been one of the so-called "drop shipments" by which Apotex Corp. arranged for drugs to be shipped to a company in the United States, that company still would have received a Notice of Detention as the consignee of the product.

Now, we heard this morning Apotex's objection to the "trinity of measures." But this is not an objection that is different from the arguments that the United States made in its Counter-Memorial. I don't believe I have time to walk through the various submissions, but I would just point you to a few references in the Parties' pleadings. Perhaps, the Tribunal could have reference to our Counter-Memorial at Paragraphs 85 and 274 where the two Measures are discussed, the U.S.'s Reply on Bifurcation at Paragraph 42, and then Apotex's Rejoinder on Bifurcation which discusses the so-called "trinity of measures." The point simply being that to the extent that Apotex did not clearly understand the United

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16:39:24 States's jurisdictional objections with respect to "relating to" and how each Measure related to or did not relate to each alleged investor or investment, it certainly understood it in its Rejoinder on Bifurcation. It certainly could have addressed this argument in its Reply. It simply declined to do.

If I might turn to the Bellarno case now, Apotex cited to this 1998 decision in Bellarno for the proposition that Import Alerts constitute automatic detentions. But it was following the Bellarno case that FDA amended the Import Alert to make clear that it did not call for automatic detention. If you look at the Import Alert in this case, Tab 33 of the Joint Core Bundle, it states at the top "The revision of this Import Alert dated August 17, 2007, changes the name of the Import Alert and removes reference to 'automatic detention.' Changes are bracketed with an ellipsis."

Thus, at the time FDA had added Etobicoke and Signet to the Import Alert, FDA had made perfectly clear on the face of the documents that the drugs were not subject to automatic detention. To the contrary,

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16:40:43 the version of the Import Alert Apotex submitted in this arbitration, which is C-110, makes clear by its terms and in bold text: "Note: This Import Alert represents the Agency's current guidance to FDA field personnel regarding the manufacturers and/or products at issue. It does not confer any rights for or on any person and does not operate to bind FDA or the public."

Further, and contrary to Apotex's suggestion this morning, the challenged Measure in this case can in no way be compared with the import permit requirement in Cargill. There, Mexico declined to give Cargill's Mexican investment in Mexico an Import Permit that it required in order to operate lawfully there. Here, by contrast, Apotex Corp. and every other supplier of drugs from Apotex Inc. in the U.S. could not sell those drugs because they were lawfully deemed to be adulterated. Cargill would have been a very different case if Mexico had found Cargill's high-fructose-corn syrup to have been adulterated and on that basis denied it importation into Mexico. But that's obviously not what happened in that case.

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16:42:02 The Tribunal determined that Mexico had devised and implemented the Import Permit requirement and the IEPS tax in order, impermissibly, to favor the Mexican sugar industry. The cases are in no way comparable.

We also heard this morning Apotex's representations that Apotex Corp. was set up specifically to market and distribute drugs manufactured by Apotex Inc. As we discussed in Paragraph 309 of our Counter-Memorial, this statement flatly contradicts statements Apotex has made when seeking to avoid jurisdiction in U.S. courts. In the AstraZeneca Case, which is cited in that paragraph in the footnote, for instance, Apotex Corp. denied that it "acts in concert with Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States."

It remains unclear to us how Apotex Corp. could have been set up specifically to market drugs from Apotex Inc. and yet not act in concert with Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical

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16:43:12 products within the United States. Nor is there any reason to conclude that the Import Alert had a legally significant connection to Apotex Corp. simply because Apotex Corp. lost 80 percent of the supplies from a foreign supplier or because labels in the United States indicate that certain drugs from Etobicoke and Signet are made by Apotex Inc. and for Apotex Corp.

By Apotex's logic, if Apotex sourced 80 percent of a product from Hospira and the Hospira facility were put on Import Alert, then Apotex Holdings could bring a NAFTA Chapter 11 claim on behalf of Apotex Corp. for those lost sales. Presumably, Apotex would introduce into evidence the labels showing that those drugs were expressly made by Hospira and for Apotex Corp. But what would be the legally significant connection between the Import Alert for Hospira and Apotex Corp.? We submit that there would be no legally significant connection there, just as there is no legally significant connection between the Import Alert and Apotex Corp.

To respond to Mr. Crook's question, the United States does invite the Tribunal to carefully

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16:44:27 evaluate each measure and each alleged investor and investment. In our view, it is perfectly clear that the sole challenged Measure in this case had no legally significant convention to an investor or investment. To the contrary, the challenged Measure had a mere incidental impact on Apotex Corp. It did not create any legal impediment to Apotex Corp.'s operations.

And to the extent that Apotex Corp. or any other company could not import drugs from Etobicoke and Signet, the underlying reason was that drugs from those facilities were lawfully deemed to be adulterated and, on that basis, could be refused admission to the United States.

If the Tribunal were to find a legally significant connection in this case, it would be creating an indeterminate class of so-called investors who could bring NAFTA Chapter 11 claims merely because they lost access to foreign supplies because those foreign suppliers failed to meet minimum U.S. regulatory requirements for the importation of goods.

The NAFTA Parties, we submit, did not create

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16:45:33 Chapter 11 to ensure against such risks.

ARBITRATOR CROOK: Before you leave Bellarno, just very quickly, and if you can't answer it off the top of your head, fine, but at the end, His Honor, Judge McGlaughin did grant Bellarno's motion for summary judgment on something. So Bellarno won some principle here. I can't tell from my quick reading what it is that he granted summary judgment for.

Can you tell us what exactly the judge upheld?

MR. SHARPE: Mr. Crook, we had some discussions with our FDA counsel during the break, but I didn't record all of that. So if it would be permissible, I'll just reconvene with her and get the right information to you.

ARBITRATOR CROOK: Thank you.

PRESIDENT VEEDER: While you're doing that, it would be very helpful to be taken through the Bellarno decision to try and extract what the relevant wording was there of the Import Alert that you say is very different from the Import Alert at issue in this arbitration.

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16:46:48 MR. SHARPE: Thank you, Mr. President.

Finally, I would like to spend a few minutes responding to five arguments made this morning on Article 1105.

First, Apotex stated that it did, in fact, allege treatment of an investment in its Memorial and Reply, but Apotex has conflated, in our view, its statements on the legal standard for Article 1105 with its factual allegations in this case. Nowhere in its submissions has it alleged facts that constitute treatment of investments as opposed to treatment of investors.

Second, Apotex points to U.S. Bilateral Investment Treaties since 2003 containing statements on due process as evidence that it's proposed customary international law rule. These agreements, however, refer to due process as part of the denial of justice, not as a general rule of due process affecting all administrative decision making. They are simply not relevant to the Tribunal's inquiry here.

Third, Apotex argues that there is no

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16:48:01 evidence in the record that Apotex's counsel advised Apotex on any of the four local remedies available to it. That is, in our view, not correct. Exhibit R-201 reflects that Apotex and its counsel discussed bringing a lawsuit against the FDA. And further communications between Apotex and its counsel have been withheld on privilege grounds and, as I understand, are not in the record.

Fourth, Apotex argues that the only way to lift an Import Alert was through re-inspection. This, of course, assumes the correctness of FDA's cGMP determinations. But if Apotex had thought that those determinations were based on mistakes and misunderstandings, the administrative remedies provided Apotex the opportunity to correct those alleged mistakes and misunderstandings.

Fifth, Apotex suggested that FDA regards itself as somehow above the law, citing Mr. Vodra's testimony for this point. This is not correct and it's not what Mr. Vodra testified to. In this regard, it's necessary to distinguish between FDA's decision to take enforcement action against a company, and the

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16:49:10 decision not to take enforcement action against a company. The former is reviewable by any of the means we've outlined throughout these proceedings.

In particular, in this case, Apotex could have challenged the detention of its products and appealed the process up to the FDA Commissioner. We've also showed how these decisions could have been brought in U.S. courts. If FDA had made a mistake and put Apotex on Import Alert with no justification, that decision was subject to challenge through several means.

On the other hand, in Mr. Vodra's testimony, starting at transcript Page 1155, he was addressing FDA's exercise of discretion not to take action against a company. Mr. Vodra made clear that even the decision--that decision is subject to very limited review, for example, for abdication of the statute for improper motives. Mr. Vodra used a particular example, President Nixon decision's not to enforce busing laws.

Mr. Vodra then explained that--Page 1157 of the transcript--"but the day-to-day decision about

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16:50:17 whether you bring a case against Company A versus Company B and whether you bring a seizure versus an injunction, whether you bring a criminal prosecution, those are--absent evidence of selective prosecution for improper motivation, are not reviewable by a federal court."

It was the decision not to take action that the U.S. Supreme Court said was not reviewable in Heckler versus Chaney. We quoted that case for you in Mr. Bigge's presentation last week which laid out various reasons such decisions are not subject to review absent circumstances that are not present here.

Mr. President, Members of the Tribunal, unless there are further questions, I would ask that you call on Ms. McLeod for final observations from the United States.

PRESIDENT VEEDER: Please. Welcome back.

Oh, we have a question.

ARBITRATOR ROWLEY: I'm sorry. I misled my President.

Mr. Sharpe, think of ANDA that has been approved in the hands of a U.S.-based pharmaceutical

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manufacturer.

What--how would you describe it? What rights does to give that U.S.-based manufacturer?

MR. SHARPE: Our understanding, Mr. Rowley, is that it doesn't have any different rights for purposes of Chapter 11 than if it were held by a foreigner or even if it were tentatively approved.

The main reason is it has certain qualities of property: It can be sold, it can be owned, and so forth. But the main distinction between property and an ANDA is that it's fully revocable by the Government for--without having to provide any property-like remedies such as payment for the taking of that property.

Now, the Government can take it for issues that concern the holder of the ANDA. For instance, if there had been misrepresentations in the application. But it can also be revoked, as I understand it, for matters wholly outside of your control. For instance, if there were issues with new scientific information about issues about the brand drug, you might lose your ANDA and you have no right to any compensation for the

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Government taking it away from you.

ARBITRATOR ROWLEY: Gotcha.

I don't mean to cut you off but it's not quite addressing the point that I want you to address.

Assume that you've got a U.S.-based pharmaceutical manufacturer who has filed an application for an ANDA and it's been granted it, and it is not subject to those matters you just mentioned. There was no deception, there had been no changes in the scientific--or relevant scientific changes. So it now has an ANDA.

Can it then manufacture and sell the drugs in question in the United States?

MR. SHARPE: Yes, it can manufacture and sell the drugs in the United States.

ARBITRATOR ROWLEY: Would it be--I know you don't like the expression "authorization to manufacture and sell," but that seems to be what it is in the hands of a U.S. owner.

MR. SHARPE: Right. I would think in the hands of a U.S. or foreign, it would be an authorization in the sense that you are permitted so

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far as that ANDA remains approved.

But even after it has been finally approved and you have been manufacturing for years, it is revocable for any of the number of reasons stated by statute.

ARBITRATOR ROWLEY: I understand.

MR. SHARPE: Okay.

ARBITRATOR ROWLEY: Now, let's think of a Canadian pharmaceutical manufacturing facilities in Canada. It applies for an ANDA and it is granted one and it's not subject to revocation at the moment because of--for scientific reasons or reasons of deception.

Does it then have an authorization to sell, manufacture for sale, those drugs in the United States?

MR. SHARPE: Yes, that's my understanding.

ARBITRATOR ROWLEY: And so it--I'll tell you why I'm pursuing this. I'm looking at the wording of the Apotex I and II reasons, and what I'm trying to come to grips with is what that Tribunal was talking about at Paragraph 224. And I don't know whether

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Paragraph 224 is handy to you or not.

MR. SHARPE: I think I know the paragraph, yes.

ARBITRATOR ROWLEY: In the second sentence the Tribunal says: The jurisdictional issue here turns upon the inherent nature of the relevant ANDAs.

And just so you know what my--what is troubling me, "the relevant ANDAs" there are the two ANDAs in question, their applications that have not been approved, not the nature of Apotex's rights over them.

And then it carries on and set out about even assuming that the ANDAs were Apotex's exclusive property, they remained no more than applications for permission in this case--or application for permission to in this case export.

And I'm wondering whether those words capture ANDAs that have been approved?

MR. SHARPE: Yes, I believe they do. I had understood this, when I read this, to be responding to Claimants' response to the United States's arguments, that we said, Members of the Tribunal, this ANDA

really in this case is operating as an export license, although it is not an export license, but this facility is overseas, and this is the cost of its selling its drugs in the United States.

And Apotex responded, as I recall, well, United States, that's not correct because an ANDA is required of anyone who wishes to sell a generic drug in the United States. So we're not subject to different regulations simply because we're in Canada versus a company in the United States.

And I had understood the Tribunal to be saying here that although it is not an export license, it has the effect of an export license in this case. That is, Apotex hadn't brought any investment to the United States in order to sell its drugs. It simply obtained this application to market those drugs, but there was no--there were no resources of investment brought to the United States in order to obtain that application that served in that case like an export license.

ARBITRATOR ROWLEY: Thank you.

MR. SHARPE: Thank you, Mr. President,

Members of the Tribunal.

PRESIDENT VEEDER: Thank you very much. Please don't feel too hurried. We've interfered with the timetable. You have at least 15 minutes left, but if you need longer, do tell us.

MS. McLEOD: Thank you.

Mr. President, Members of the Tribunal, I'm pleased to have the opportunity to close the United States's arguments in these proceedings. I regret that I wasn't able to attend all of last week's proceedings, but I have read the transcripts with great interest. As I stated a week ago, I am appearing in these proceedings not simply to highlight important Legal Arguments for the United States, but also to emphasize the importance of the case to the U.S. Government.

As I reflected on the case over the weekend, I thought about the difficult position that FDA often finds itself in, weighing decisions that literally have life-and-death consequences for millions of American consumers. I thought about the challenges the Agency faces when balancing drug safety against

drug availability. And I thought about the competing pressures FDA faces to follow U.S. laws and regulations; to work with drug companies to try avoid dangerous shortages of safe and effective drugs; and to adapt to a now-globalized pharmaceutical industry.

To Apotex and its legal Experts, FDA's choices appear very simple. In presenting its case, Apotex reviewed three-page Warning Letters, tallied the violations identified, and drew legal conclusions about who received better or worse treatment. Apotex's simplistic analysis, however, does not approach the task that FDA faces. It does not grapple with FDA's challenges, and, therefore, does not grapple with weighing the risk factors FDA has to deal with in these challenges. Apotex simply lacks the expertise, knowledge, and information to do so.

At the same time, Apotex appears not to want to take any responsibility for why its drug products were deemed adulterated or to try to understand the basis for FDA's concerns about its manufacturing practices. Apotex, for example, acknowledges that it often failed to submit Field Alert Reports on time,

and that some of them were filed more than a year late. But it dismisses these serious violations of U.S. law as mere paperwork violations.

Further, Apotex acknowledges that it recalled 640 batches of 42 different drugs from the U.S. market for cGMP problems. But it claims to have done so not to protect U.S. consumers from adulterated drugs, but as a mere goodwill gesture to FDA. And yet, when FDA has declined to take action against other companies, Apotex and its Experts are quick to assume that FDA has acted arbitrarily.

Ben Venue's Ohio facility provides a perfect example. As you heard last week, FDA found serious cGMP problems at that facility, but the Agency declined to take immediate enforcement action. Health Canada and the EU, by contrast, quickly blocked importation of drugs from that facility into Canada and Europe.

Mr. Bradshaw and Mr. Johnson drew the following conclusion: "It is remarkable that, while--sorry; "it is remarkable that while the U.S. claims that FDA is a worldwide leader in regulating

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17:01:56 drugs for public health, FDA filed a complaint against Ben Venue and entered into a Consent Decree only in late January of 2013, over a year after Canadian and EU regulators imposed their respective bans on the firm's products. In our view, this shows that FDA is applying its discretion in an arbitrary manner." And this is a quote from the second Bradshaw Report, Paragraph 58. That's Messrs. Bradshaw and Johnson's professional view.

This may seem like a reasonable inference from their vantage, but it's an inference drawn from two data points. It compares FDA's actions against the actions of Canada and the EU and then draws a definitive legal conclusion. What's missing from this legal conclusion is any consideration of the other factors in FDA's risk-based approach, including shortages of medically necessary drugs.

Let me read from this February 10, 2012, article from the New York Times, which makes the point very well. The title is "Supply of a Cancer Drug May Run Out Within Weeks." "A crucial medicine to treat childhood leukemia is in such short supply that

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17:03:08 hospitals across the country may exhaust their stores within the next two weeks leaving hundreds and perhaps thousands of children at risk of dying from a largely curable disease, federal officials and cancer doctors say. 'This is dire,' said Valerie Jensen, Associate Director of the Food and Drug Administration's Drug Shortages program. 'Supplies are just not meeting demand.'

"The drug is methotrexate, and the cancer it treats is known as acute lymphoblastic leukemia or ALL, which most often strikes children ages 2 to 5. It is an unusually virulent cancer of white blood cells that are overproduced in bone narrow and invade other parts of the body.

"Ben Venue Laboratories was one of the nation's largest suppliers of injectable preservative-free methotrexate, but the company voluntarily suspended operations at its plant in Bedford, Ohio, in November, because of 'significant manufacturing and quality concerns,' the company announced.

"Since then, supplies of methotrexate have

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17:04:13 gradually dwindled to the point where oncologists now say they are fearful that shortfalls may occur at many hospitals within two weeks.

"'This is a crisis that I hope the FDA's hard work can help to avert,' said Dr. Michael P. Link, President of the American Society of Clinical Oncology. 'We've worked very hard to take what was an incurable disease and make it curable for 90 percent of the cases. But if we can't get this drug anymore, that sets us back decades.'"

This article helps explain why FDA sought to prevent Ben Venue from immediately shutting down its Ohio facility. And I ask you: Could any reasonable observer state, as Messrs. Bradshaw and Johnson have stated, that FDA's action "shows that FDA is applying its discretion in an arbitrary manner"?

It is always easy to second-guess, to draw inferences from incomplete facts, to see the world in black and white. But FDA does not have the luxury to choose black or white, to always prioritize drug safety over drug availability. FDA has to make difficult choices, and it is not always clear to those

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17:05:21 outside looking in to understand what factors tilted the scale in one direction or the other.

But simply because one does not understand precisely why a decision was made does not make that decision arbitrary. This is why U.S. courts generally refuse to hear challenges to FDA's decision not to take enforcement action because such actions are committed to Agency discretion by law.

The fact that different drug authorities around the world reacted differently to Apotex's manufacturing problems shows that there's no one correct or legal response to similar cGMP problems. On one end is New Zealand's Medsafe. Medsafe reviewed FDA's findings and Apotex's response to those findings. Medsafe then informed Apotex that if Apotex had been a New Zealand company, Medsafe would have shut them down.

On the other end is Health Canada. Health Canada performed its own inspections at Etobicoke and Signet in the fall of 2009. Health Canada found more violations and arguably more serious violations than even FDA had found at either facility. Undoubtedly,

17:06:33 Health Canada was alarmed to have found that Apotex was fabricating toxic and nontoxic material without taking precautions to prevent cross-contamination. And certainly Health Canada found it unacceptable for Apotex to have repackaged for Canada drugs that had failed testing for the United States.

In fact, Health Canada identified so many serious problems that, under Canadian law, the Agency could have stripped Apotex of its operating license and shut down its facilities. But Health Canada opted not to do so. Instead, Health Canada devoted extraordinary resources to ensuring that Etobicoke and Signet remained open and that they continued producing drugs for the Canadian market.

As outsiders to their decision making, we can't know all of the reasons that motivated that decision. But we do know that Canada was then facing a national drug shortage crisis and we know that one in five prescriptions in Canada reportedly is filled with an Apotex drug. None of us, therefore, is in a position to criticize Health Canada for not having shut down Etobicoke and Signet.

17:07:39 There is a middle ground between shutting a facility down and continuing to allow production while problems are being fixed, and that is temporarily suspending importation. That is the approach that FDA chose. After applying FDA's risk factors, the Agency deemed it most appropriate to add Etobicoke and Signet to the Import Alert. Health Canada and Medsafe viewed the issues differently, but their responses were no less legitimate.

Mr. President, Members of the Tribunal, Apotex suggested that the United States was making policy arguments because it is struggling with the law or the facts. Nothing could be further from the truth. In fact, the purpose for the broader factual and policy context I and my colleagues have presented is twofold: First, it provides the context in which Apotex's flagrant conduct with respect to cGMP practices and the serious charges it has levied against the FDA should be considered; second, the United States is confident that the arguments the United States presented on the law and facts are unquestionably consistent with the intent of the NAFTA

17:08:49 Parties, as reflected in the text of the NAFTA.

Apotex rightly points out that in Article 1108 the Parties to the NAFTA had the ability to except certain measures from the National Treatment, Most-Favored-Nation Treatment, and the Minimum Standard of Treatment protections and questioned why the United States had not excepted the FDA's Measures if they were so sensitive.

The simple answer is that there was no need to do so based on the text of the NAFTA. But here, where Apotex has stretched the limits of the jurisdictional and substantive provisions of the NAFTA to advance its claims beyond what was ever contemplated by the Parties, we feel compelled to raise the significant policy consequences that would ensue from an Award based on Apotex's faulty arguments.

As I stated last week, the NAFTA Parties did not intend for investment Tribunals to sit retrospectively in judgment of the discretionary exercise of the sovereign power in the manner Apotex suggests. This is particularly true with regard to

17:09:52 the protection of health and well-being of that Sovereign's citizens, and where there is no evidence that the FDA acted arbitrarily or applied its risk-based approach any differently to Apotex than to other countries [sic].

This is especially true here, where that authority was exercised in accordance with long-standing domestic law and well-established FDA practice, where Agency personnel exercised their regulatory authority in good faith, and where the decisions were made rationally in light of all available information. Again, there is nothing in the record of this case that suggests, much less demonstrates, the contrary.

Apotex impermissibly seeks to create a presumption that every time FDA issues a Warning Letter and places a generic drug manufacturer's facility on Import Alert, it has violated international law unless it can justify every instance when it has issued a warning letter and not placed the facility on Import Alert or taken other action.

But FDA often issues Warning Letters without

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17:10:55 then issuing an Import Alert or taking other action. Apotex's presumption would impose an unworkable burden on the Agency to produce sensitive documentation that would fully capture the factors that the Agency considered about other firms. Apotex, not the U.S. Government, bears the burden of proving its claims, and it has failed to do so here.

Throughout these proceedings, Apotex has impermissibly sought to push the boundaries of Chapter 11 jurisdiction. It has asserted an investment where there is none. It has put forward claims based on Measures that do not relate to the only investment in this case. And it has asserted breaches of international law in ordinary regulatory decision making, rather than demonstrated that it was accorded less favorable treatment or denied the Minimum Standard of Treatment. You have heard nothing this past week that would justify granting Apotex the relief it seeks.

Members of the Tribunal, for all the reasons set out in the United States's pleadings and oral argument, we respectfully request that you: One,

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17:12:03 dismiss with prejudice all claims of Apotex Holdings Inc. and Apotex Inc. for lack of jurisdiction; two, if jurisdiction is found, dismiss with prejudice all claims of Apotex Holdings and Apotex Inc.; and, three, order that Apotex bear all costs of the proceedings, including the United States's costs for legal representation and assistance.

We also invite the Tribunal to order the Parties to make their cost submissions within a reasonable time following these proceedings, perhaps by mid-January, so that final invoices can be obtained from Experts.

Mr. President, Members of the Tribunal, this concludes the Respondent's closing statement. On behalf of United States, I wish to thank ICSID, particularly Mr. Taylor, for superb support throughout these proceedings, Ms. Larson, for her patience and able assistance, and the Tribunal for their careful consideration in this matter.

Thank you very much.

PRESIDENT VEEDER: Thank you very much, too. We have no questions at this stage.

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17:13:14 So we come to the end of today, and under our order last Friday, we come back for 9:00 tomorrow to hear the Closing Reply Submissions from the Claimant. And then, after a break, the Closing Reply Submissions from the Respondent.

There is a certain amount of housekeeping which we will need to address tomorrow. So we raise it now simply because it may be agreeable for the Parties to come to some agreement about that.

The question of costs has just been raised. If mid-January is what you both have in mind for the first round of cost submissions, that would be approved by the Tribunal. But we think it may go beyond that. And again, please don't read into this. You're asking for costs, both if we make a decision, and costs if we're asked for an Award.

But since the questions of cost go both to allocation as reasonableness in amount, then I think you should have a right of Reply to the other Party's cost submissions, simply--effectively, looking at the overall quantum, whether the sum has been reasonably incurred in a reasonable sum. So we need to look for

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17:14:34 a date, I think, for a short response. It need not be a very long delay, but it would be a week or two weeks, I suspect. So could you think about that.

We've had marvelous service as regards to transcript, but we would like to feel confident within a week or so we are working off a transcript that was not subject to any egregious error which later a Party might wish to raise. So we'd like to put a time limit on a final check through the transcript. Don't worry about small things, but if there's a negative missing, it tends to be quite important for that to be drawn to our attention.

That was all we had by way of housekeeping. We'd like to come back to that, obviously, at end of tomorrow.

Is there anything else--we ask the Claimants first--that we need to address before we depart tomorrow lunchtime?

MR. LEGUM: I think for the time being, Mr. President, the Claimants would simply join in the United States's thanks to ICSID for superb support and to the Tribunal for its careful attention. We'll

consider these issues and come back to the Tribunal.

PRESIDENT VEEDER: Thank you for that, too.

On the Respondent's side, is there any outstanding housekeeping we need to think about before we close the hearing at midday or lunchtime tomorrow?

MS. GROSH: No outstanding issues at this time, Mr. President.

PRESIDENT VEEDER: Well, we will see you tomorrow at 9:00. Thank you all very much.

(Whereupon, at 5:15 p.m., the hearing was adjourned until 9:00 a.m. the following day.)

CERTIFICATE OF REPORTER

I, Dawn K. Larson, RDR, Court Reporter, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

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DAWN K. LARSON